FORMS VERSION D SERIES UPDATED MARCH 24, 2017



FELLOWSHIP INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) APPLICATION PACKAGES

Guidance developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

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F.100 - How to Use the Application Instructions

Use these application instructions to fill out the forms that are posted in your funding opportunity announcement.

Take a tour of the Application Guide

Quick Links

- Step 1. Become familiar with the application process
- Step 2. Use these instructions, together with the forms and information in the FOA, to complete your application
- Step 3. Choose an application instruction format
- Step 4. Complete the appropriate forms
- Step 5. Stay informed of policy changes and updates

Helpful Links

The information on the following pages may be useful in the application process

- OER Glossary
- Supplemental Grant Application Instructions
- Grants Policy Statement
- Guide to Grants and Contracts
- Frequently Asked Questions

Step 1. Become familiar with the application process.

Understanding the application process is critical to successfully submitting your application.

Use the <u>F.110 - Application Process</u> section of these instructions to learn the importance of completing required registrations before submission, how to submit and track your application, where to find page limits and formatting requirements, and more information about the application process.

Step 2. Use these instructions, together with the forms and information found in the funding opportunity announcement, to complete your application.

The funding opportunity announcement (FOA) will include specific instructions and the forms needed for your application submission.

Remember that the FOA instructions always supersede these application instructions.

Step 3. Choose an application instruction format.

Do you know your activity code, but don't know which application instructions to use? Refer to NIH's table on <u>Selecting the Correct Application Instructions</u> to determine which set of application instructions applies to your grant program.

Comprehensive Instructions	Program-Specific Instructions
Use the General (G) instructions, available in both HTML and PDF format, to complete the application forms for any type of grant program.	Take advantage of the filtered PDFs to view specific application instructions for: • Research (R) • Career Development (K) • Training (T) • Fellowship (F) • Multi-project (M) • SBIR/STTR (B)

Step 4. Complete the appropriate forms.

Unless otherwise specified in the FOA, follow the **standard instruction**, as well as any additional **program-specific** instructions for each form in your application.

Program-specific instructions are presented in gray call-out boxes that are color coded throughout the application instructions. Consult the <u>F.130 - Program Overview</u> section for context for program specific instructions.

Step 5. Stay informed of policy changes and updates.

- Refer to the <u>F.120 Significant Changes</u> section for the most recent changes to these application instructions.
- Review Notices of NIH Policy Changes since the posting of the Application Guide.

F.110 - Application Process

Understanding the application process is critical to successfully submitting your application. Use this section of this guide to learn the importance of completing required registrations before submission; how to submit and track your application; where to find information about page limits, formatting requirements, due dates, and submission policies; and more information about the application process. This application process information is also available on our How to Apply – Application Guide page.

Quick Links

- Prepare to Apply
- Write Application
- Submit
- Related Resources

Prepare to Apply and Register

Systems and Roles

Learn about the main systems involved in application submission and the role you and your colleagues play in the submission process. The main systems are <u>Grants.gov</u>, <u>eRA Commons</u>, and ASSIST.

Register

Determine your registration status. Organizations, organizational representatives, investigators, and others need to register in multiple federal systems in order to for you to submit a grant application. Registration can take six weeks or more to complete. Start today! See NIH's Registration website.

Understand Funding Opportunities

Identify the right funding opportunity announcement (FOA) for your research and learn about key information you will find in the FOA.

Types of Applications

Are you submitting a new, renewal, revision, or resubmission application? Learn about the different types of applications and special submission requirements.

Submission Options

Determine which system is most convenient for your application submission: NIH's ASSIST webbased application submission system, Grants.gov downloadable forms, Grants.gov Workspace, or, if applicable, your organization's own submission system.

Obtain Software

Applicants must have the free Adobe Reader software, a PDF generator, and a web browser to submit an application. Learn which versions are compatible with our systems.

Write Application

Write Your Application

Read tips for developing a strong application that helps reviewers evaluate its science and merit.

Develop Your Budget

Learn about the kinds of costs you may include in your budget submission, the difference between modular and detailed budgets, and more about how to develop your budget.

Format Attachments

Follow these requirements for preparing the documents you attach to your application. Requirements include criteria for the PDF files, fonts, margins, headers and footers, paper size, citations, formatting pages, etc.

Page Limits

Follow the page limits specified in this table for your specific grant program, unless otherwise specified in the FOA.

Data Tables

Find instructions, blank data tables, and samples to use with institutional research training applications.

Reference Letters

Some types of programs, such as fellowships and some career development awards, require the submission of reference letters by the referee. Learn about selecting a referee and find instructions for submission.

Biosketches

Biosketches are required in both competing applications and progress reports. Find instructions, blank format pages, and sample biosketches.

Submit

Submit, Track and View

Learn how to submit your application, and about your responsibility for tracking your application and viewing the application image in the eRA Commons before the application deadline. If you can't view your application in eRA Commons, we can't review it.

How We Check for Completeness

Your application will be checked at Grants.gov, by eRA systems, and by federal staff before it is referred for review.

Changed/Corrected Applications

You will need to submit a changed/corrected application to correct issues that either you or our systems find with your application. Learn how and when you may submit a change/corrected application.

Related Resources

Due Dates and Policies

Due Dates

View standard due dates for competing applications. The FOA will identify whether to follow standard due dates or whether to follow an alternative due date.

Submission Policies

Learn the nuances of application submission policies, including when late applications might be allowed, what to do if due dates fall on a weekend or holiday, whether we allow post-submission materials, how to document system issues, the rules around resubmission applications, etc.

Dealing with System Issues

Are you experiencing system issues with ASSIST, Grants.gov, System for Award Management (SAM), or the eRA Commons that you believe threaten your ability to submit on time? NIH will not penalize applicants who experience confirmed issues with federal systems that are beyond their control. You must report the problem before the submission deadline.

After Submission

Receipt and Referral

Understand how and when applications are given an application identification number and assigned to a review group and an NIH Institute or Center (IC) for possible funding.

Peer Review

Learn about our two phase peer review process, including initial peer review, Council review, review criteria, scoring, and summary statements.

Pre-award Process

Learn what happens between peer review and award for applications that have been deemed highly meritorious in the scientific peer review process. Be ready: if you received a great score in peer review, you'll have to submit Just-in-Time information.

Post award Monitoring and Reporting

If you receive a grant from the NIH, you will need a lot of information to be a successful steward of federal funds. This page provides a brief overview of grantee monitoring and reporting requirements.

Resources

News - Items of Interest

The NIH eSubmission Items of Interest page provides comprehensive information, in an informal format, on the changes impacting application development and submission.

Annotated Form Sets

These handy documents are a great visual resource for understanding many of the validation checks we will run against your submitted application.

Contacting NIH Staff

NIH staff is here to help. We strongly encourage NIH applicants and grantees to communicate with us throughout the grant life cycle. Understanding the roles of NIH staff can help you contact the right person at each phase of the application and award process.

Contacting Staff at Other PHS Agencies

Applicants are strongly encouraged to communicate with agency staff throughout the entire application review and awards process.

Systems

ASSIST

eRA Commons

Grants.gov

Information Collection

Authorization

The PHS Act establishes the authority with which NIH and other PHS agencies award grants and collect information related to grant awards.

Paperwork Burden

The paperwork burden provides the estimated time for completing a grant application.

Collection of Personal Demographic Data

NIH collects personal data through the eRA Commons Personal Profile. The data is confidential and is maintained under the Privacy Act record system.

F.120 - Significant Changes

The Application Instructions are updated and released 2-3 times per year as needed. Additionally, minor revisions may be made outside of these releases.

This section details all significant changes and revisions made to the instructions since the last major release.

Within the instructions, new instructions will be marked with this symbol.

In the web version, use your mouse to hover over the icon to read an explanation of the change.

In a PDF version, this symbol will be visible but will not display hover text. For more information, see the explanation in the Significant Changes section below.

Release Notes - March 24, 2017

How to Apply - Application Guide and Format Page Changes

- Implemented minor layout and design changes to the How to Apply page in order provide a more streamlined look and feel.
- Minor clarifications made to the predoctoral fellowship biosketch sample.
- Minor clarifications to the instructions for the institutional training grant data tables, including:
 - Table 1 Added guidance for resubmission applications following a gap in funding.
 - Table 3 Added instructions for applicants to describe any relevant restrictions on existing support for research training.
 - Table 4 Added clarification for how to report research support for faculty serving as Project or Core Leads on multi-project grants or cooperative agreements.

Form Instruction Changes

R&R Other Project Information Form

• Incudes addition of interim research products as allowable citations. See the NIH Guide Notice on Interim Research Products for more information.

R&R Senior/Key Person Profile (Expanded) Form

• Includes addition of interim research products as allowable citations. See the NIH Guide Notice on Interim Research Products for more information.

PHS Fellowship Supplemental Form

- Removed old appendix instructions. See the NIH Guide Notice on <u>Allowable Appendix Materials</u> for more information.
- Includes addition of interim research products as allowable citations. See the NIH Guide Notice on Interim Research Products for more information.

PHS Assignment Request Form

• Clarified how to report potential conflicts of interest among reviewers in <u>F.600 - PHS Assignment</u> Request Form.

Release Notes - November 22, 2016

How to Apply - Application Guide and Format Page Changes

- Included direct hyperlinks to the Data Tables, Reference Letters, and Biosketch Format Pages under the Format and Write box.
- Updated the blank Biosketch Format Pages to include the required headings for Sections A-D

Plain Language Edits to Application Instructions

- Implemented a new format and structure for application instructions. Overall policies did not change; the purpose was to enhance clarity of existing instructions.
 - Examples of plain language edits include:
 - Rewritten instructions for enhanced clarity and ease of understanding.
 - Consistent use of headings make information easy to find (e.g., "Who must complete this section/attachment," "Format," "Content," "For more information").
 - Clear delineations between instructions and supporting information.
 - Clarified what is required and optional throughout the instructions.

Form Instruction Changes

R&R Senior/Key Person Profile (Expanded) Form

- Clarified biosketch instructions for research, institutional research training, institutional career development, research education, fellowship, and dissertation awards, as well as diversity supplements.
- Clarified that figures, tables, or graphics are not allowed in the Biosketch. Previous instructions noted this only under "Section A. Personal Statement." This is not a policy change, but a clarification of instructions.

PHS Fellowship Supplemental Form

 Includes the new appendix policy that goes into effect for applications due on or after January 25, 2017. This policy redefines the allowable appendix materials. See the NIH Guide Notice on Allowable Appendix Materials for more information.

Revision Notes - June 10, 2016

- Formatting changes to <u>F.100 How to use the Application Instructions</u>.
- Corrected typos throughout instructions for greater clarity.
- Removed language regarding the 1 page limit for career development applications in the Project Summary/Abstract field in <u>F.220 - R&R Other Project Information Form</u>. The standard instruction of no more than 30 lines of text applies.

Release Notes - March 25, 2016

Application Guide Restructure

- **Forms reordered.** Form instructions have been reordered to match the order of appearance in the application package.
- **Consolidated instructions.** SBIR/STTR instructions have been incorporated into the general instructions.
- **Separated form instructions from application process information.** Created an application guide landing page that provides at-a-glance access to all form instructions and application process information. Links to all grants process information appear in the form instructions as well.
- Combined and streamlined instructions. For Research and Related (R&R) forms, we have combined Federal-wide and agency-specific instructions to reduce confusion, contradictions, and/or redundant language. Users will no longer see the HHS logo displayed, as all instructions are now applicable to NIH and PHS agencies.
- **Better integrated mechanism-specific instructions.** Variances in instructions for each type of grant program (research, career development, etc.), are now called out and integrated in the general instructions to make them easy to follow.
- New mechanism-specific views of application guide. Use the General (G) instructions to see instructions for all mechanisms in one place. Take advantage of the filtered views to see just the instructions you need for research (R), career development (K), training (T), fellowship (F), multiproject (M) or SBIR/STTR (B) applications.
- New section numbering system. Form instructions will follow the same numbering system for each set of instructions. For example, the SF 424 (R&R) Cover Form will always be ".100," and the letter preceding it will reflect the specific instructions you are using. For the General (G)

instructions, this form will be located in G.100; for the Research (R) instructions, this will be R.100; and so on.

- **New page numbering system.** Page numbers will denote which set of instructions you are looking at (e.g., G 56 for page 56 of the General instructions; R 56 for page 56 of the Research (R) instructions; etc.). This distinction will be important when you reference a particular instruction.
- Form screenshots. Provided at the end of each set of instructions for your reference.

SF424 Research and Related (R&R) Form Changes

R&R Other Project Information Form

 A list of referees is no longer required as an Other Attachment on the R&R Other Project Information Form. This information is only required in the cover letter attachment. Reference letters will continue to be submitted through eRA Commons.

R&R Senior/Key Person Profile (Expanded) Form

- Mentors must provide a Commons username for Career applications (See NIH Guide Notice on Change in the Application Process for Individual Mentored K Awards)
- Consolidated biosketch instructions for research, institutional research training, institutional
 career development, research education, fellowship, and dissertation awards, as well as diversity
 supplements. Clarified policy requirements. See NIH Guide Notice on <u>Clarifications and</u>
 Consolidated Biosketch Instructions and Format Pages.

Forms-D Changes

PHS Assignment Request Form

- New, optional form
- Provides structured information to NIH referral staff regarding: funding component assignment preference, study section preference, individuals who should not review your application due to conflicts, and scientific areas of expertise needed to review your application
- Complements existing "Cover Letter Attachment" on SF424 (R&R) form
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Fellowship Supplemental Form

- New "Applicant's Background and Goals for Fellowship Training" attachment
 - Combines "Doctoral Dissertation and Other Research Experience," "Goals for Training and Career," and "Activities Planned Under Award" attachments into a single attachment
- New "Letters of Support from Collaborators, Contributors, and Consultants" attachment
- New "Description of Institutional Environment and Commitment to Training" attachment
- New "Data Safety Monitoring Plan" attachment

- New "Authentication of Key Biological and/or Chemical Resources" attachment
- New Vertebrate Animals questions added:
 - Are animals euthanized? Yes/No
 - If Yes, is method consistent with AVMA guidelines? Yes/No
 - If No to AVMA guidelines, describe method/provide scientific justification
- Updated list of values for the "Field of Training for Current Proposal" field; changed from 4-digit codes to 3-digit codes
- Updated Citizenship selections
- Reorganization of attachments
- · Format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Inclusion Enrollment Report

- Combines Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms into a single form
- Questions used to identify type of report:
 - Delayed onset study? Yes/No
 - Enrollment Type? Planned/Cumulative (Actual)
 - Using an Existing Dataset or Resource? Yes/No
 - Enrollment Location? Domestic/Foreign
 - Clinical Trial? Yes/No
 - NIH-Defined Phase II Clinical Trial? Yes/No
- Added/updated burden statement and form expiration date
- Updated form instructions

F.130 - Program Overview

Quick Links

- Individual Fellowship Applications ("F" Series)

Individual Fellowship Applications ("F" Series)

The purpose of individual fellowship awards is to provide individual research training opportunities to fellows at the graduate and postdoctoral levels. This section contains information for preparing Kirschstein-NRSA (NRSA) fellowship and non-NRSA fellowship applications.

Additional Instructions for Fellowship:

Additional fellowship instructions will be denoted by a gray call-out box with orange color coding and with the heading "Additional Instructions for Fellowship" throughout these application instructions.

NRSA Programs: The 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. 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.

Non-NRSA Programs: Fogarty International Center (FIC) and National Library of Medicine (NLM) also have unique funding authorities for fellowships that are not under the NRSA authority. Note that non-NRSA programs may have eligibility requirements, due dates, award provisions, and review criteria that differ from those of NRSA programs. Applicants should refer to their FOA.

Reference Letters: Instructions for submitting the required reference letters for applicable programs are not contained in these application instructions. Instead, follow the instructions on NIH's Reference Letters page. Referees must submit reference letters through the eRA Commons by the application due date.

Payback Service Requirement: For NRSA programs that include postdoctoral fellows, the program director must explain the terms of the payback service requirement to all prospective postdoctoral fellowship candidates. A complete description of the service payback obligation is available in the NIH Grants Policy Statement, Section 14.2 on Payback Requirements.

Before Applying:

Become familiar with Activity Code: Applicants should become familiar with the "F" activity code for which support is being requested. A listing of "F" series activity codes, with their descriptions, is available on the NIH <u>F Kiosk</u> and the <u>AHRQ-Sponsored</u> <u>Training Opportunities</u> page.

- 2. Refer to your specific FOA: Refer to your specific FOA for specific information associated with the award mechanism, including the eligibility requirements, requirements for a mentor, review criteria, award provisions, any special application instructions, and names of individuals who may be contacted for additional or clarifying information prior to application submission.
 - FOAs and other guidelines are available on the NIH F Kiosk.
 - Guidelines for the AHRQ fellowships may be found on AHRQ's Research Training and Education website.
- 3. **Contact Awarding Component:** Applicants are encouraged to consult with the appropriate NIH IC or AHRQ staff prior to submitting an application, as not all predoctoral, postdoctoral, and senior fellowships are supported by each IC or AHRQ.
 - A list of contacts specifically for extramural training at the NIH ICs can be found on the NIH Training Advisory Committee Roster.
 - For contacts at AHRQ, see AHRQ's Research Training Staff Contacts website.

The following chart provides a list of fellowship activity codes. Since this information is subject to change, prospective applicants are encouraged to review the <u>F Kiosk</u> for the most current program information.

Summary of Individual Fellowship Award Programs

Activity Code	Program Description	NRSA?
F05	International Research Fellowships	No
F30	Individual Predoctoral National Research Service Award (NRSA) for M.D./Ph.D. and Other Dual Degree Fellowships	Yes
F31	Predoctoral Individual National Research Service Award	Yes
F32	Postdoctoral Individual National Research Service Award	Yes
F33	National Research Service Awards for Senior Fellows	Yes
F37	Medical Informatics Fellowships	No
F38	Applied Medical Informatics Fellowships	No
F99/K00	Individual Predoctoral to Postdoctoral Fellow Transition Award	No

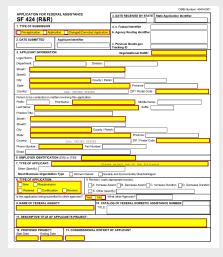
F.200 - SF 424 (R&R) Form

The SF 424 (R&R) Form is used in all grant applications. This form collects information including type of submission, applicant information, type of applicant, and proposed project dates.



Quick Links

- 1. Type of Submission
- 2. Date Submitted and Applicant Identifier
- 3. <u>Date Received by State and State Application</u> <u>Identifier</u>
- 4a. Federal Identifier
- 4b. Agency Routing Identifier
- 4c. Previous Grants.gov Tracking ID
- 5. Applicant Information
- 6. Employer Identification
- 7. Type of Applicant
- 8. Type of Application
- 9. Name of Federal Agency
- Catalog of Federal Domestic Assistance Number and Title
- 11. Descriptive Title of Applicant's Project
- 12. Proposed Project
- 13. Congressional District of Applicant
- 14. <u>Project Director/Principal Investigator Contact Information</u>
- 15. Estimated Project Funding
- 16. <u>Is Application Subject to Review by State Executive</u>
 Order 12372 Process?
- 17. Certification
- 18. <u>SFLLL</u> (Disclosure of Lobbying Activities) or Other <u>Explanatory Documentation</u>
- 19. Authorized Representative
- 20. Pre-application
- 21. Cover Letter Attachment



1. Type of Submission

This field is required. Check one of the "Type of Submission" boxes:

Pre-application:

The pre-application option is not used by NIH or other PHS agencies unless specifically noted in a funding opportunity announcement (FOA).

Application:

An "Application" is a request for financial support of a project or activity submitted on specified forms and in accordance with NIH instructions. (See NIH <u>Types of Applications</u> for an explanation of the types of applications).

Changed/Corrected Application:

Check this box if you are correcting either system validation errors or application assembly problems that occurred during the submission process. Changed/corrected applications must be submitted before the application due date.

When you submit a changed/corrected application, follow these guidelines:

- After submission of an application, there is a two-day application viewing window. Prior to the
 due date, you may submit a changed/corrected application. Submitting a changed/corrected
 application will replace the previous submission and remove the previous submission from
 consideration.
- If you check the "Changed/Corrected Application" box, then "Field 4.c Previous Grants.gov Tracking ID" is required.
- Do not use the "Changed/Corrected Application" box to denote a resubmission application. Resubmission applications will be indicated in "Field 8. Type of Application." See NIH Glossary for the definition of Resubmission.

2. Date Submitted and Applicant Identifier

The "Date Submitted" field will auto-populate upon application submission.

Fill in the "Applicant Identifier" field, if applicable. The Applicant Identifier is reserved for applicant use, not the federal agency to which the application is being submitted.

3. Date Received by State and State Application Identifier

Skip the "Date Received by State" and "State Application Identifier" fields.

4.a. Federal Identifier

New Applications without Pre-application: Leave this field blank.

New Applications following Pre-application: Enter the agency-assigned pre-application number.

Resubmission, Renewal, and Revision Applications: The Federal Identifier is required. Include only the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1).

4.b. Agency Routing Identifier

Skip the "Agency Routing Identifier" field unless otherwise specified in the FOA.

4.c. Previous Grants.gov Tracking ID

The "Previous Grants.gov Tracking ID" field is required if you checked the "Changed/Corrected Application" box in "Field 1. Type of Submission." A Tracking ID number is of the form, for example, GRANT12345678.

5. Applicant Information

The "Applicant Information" fields reflect information for the applicant organization, not a specific individual.

Organizational DUNS:

This field is required.

Enter the DUNS or DUNS+4 number of the applicant organization.

This DUNS or DUNS+4 number must match the number entered in the eRA Commons Institutional Profile (IPF) for the applicant organization. The applicant's Authorized Organization Representative (AOR) is encouraged to confirm that a DUNS has been entered into the eRA Commons IPF prior to application submission. The same DUNS should be used in the eRA Commons IPF, Grants.gov, System for Award Management (SAM) registration, and in the DUNS field in the application.

If your organization does not already have a DUNS number, you will need to go to the <u>Dun & Bradstreet</u> website to obtain the number.

Legal Name:

Enter the legal name of the organization.

Department:

Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization.

Division:

Enter the name of the primary organizational division, office, major subdivision, or equivalent level within the organization.

Street1:

This field is required. Enter the first line of the street address for the applicant organization.

Street2:

Enter the second line of the street address for the applicant organization.

City:

This field is required. Enter the city for the address of the applicant organization.

County/Parish:

Enter the county/parish for the address of the applicant organization.

State:

This field is required if the applicant organization is located in the United States or its territories. Enter the state or territory where the applicant organization is located.

Province:

If "Country" is Canada, enter the province of the applicant organization; otherwise, skip the "Province" field.

Country:

This field is required. Select the country for the address of the applicant organization.

ZIP/Postal Code:

The ZIP+4 is required if the applicant organization is located in the United States. Otherwise, the postal code is optional. Enter the ZIP+4 (nine-digit postal code) or postal code of the applicant organization.

Person to be contacted on matters involving this application

This information is for the administrative contact (e.g., AOR or business official), not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made.

Prefix:

Enter or select the prefix, if applicable, for the name of the person to contact on matters related to this application.

First Name:

This field is required. Enter the first (given) name of the person to contact on matters related to this application.

Middle Name:

Enter the middle name of the person to contact on matters related to this application.

Last Name:

This field is required. Enter the last (family) name of the person to contact on matters related to this application.

Suffix:

Enter or select the suffix, if applicable, for the name of the person to contact on matters related to this application.

Position/Title:

Enter the position/title for the person to contact on matters related to this application.

Street1:

This field is required. Enter the first line of the street address for the person to contact on matters related to this application.

Street2:

Enter the second line of the street address for the person to contact on matters related to this application.

City:

This field is required. Enter the city for the address of the person to contact on matters related to this application.

County/Parish:

Enter the county/parish for the address of the person to contact on matters related to this application.

State:

This field is required if the person to contact on matters related to this application is located in the United States or its Territories. Enter the state or territory where the person to contact on matters related to this application is located.

Province:

If "Country" is Canada, enter the province for the person to contact on matters related to this application; otherwise, skip the "Province" field.

Country:

Select the country for the address of the person to contact on matters related to this application.

ZIP/Postal Code:

The ZIP+4 is required if the person to contact on matters related to this application is in the United States. Otherwise, the postal code is optional. Enter the ZIP+4 (nine-digit postal code) or postal code of the person to contact on matters related to this application.

Phone Number:

This field is required. Enter the daytime phone number for the person to contact on matters related to this application.

Fax Number:

Enter the fax number for the person to contact on matters related to this application.

E-mail:

Enter the e-mail address for the person to contact on matters related to this application. Only one e-mail address is allowed, but it may be a distribution list.

6. Employer Identification

This field is required.

Enter either the organization's Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) as assigned by the Internal Revenue Service. If your organization is not in the United States, enter 44-44444444. Your EIN may be 12 digits, and if this is the case, enter all 12 digits.

7. Type of Applicant

This field is required.

In the first field under "7. Type of Applicant," enter the appropriate applicant type. If your applicant type is not specified (e.g., for eligible Agencies of the Federal Government), select "X: Other (specify)," and indicate the name (e.g., the appropriate federal agency) in the space below.

Additional Instructions for Fellowship:

The information in "7. Type of Applicant" is for the applicant organization, not a specific individual authorized organization representative (AOR) or fellowship PD/PI.

Other (Specify):

Complete only if "X. Other (specify)" is selected as the "Type of Applicant."

Women Owned:

Check this box only if both "Small Business" is selected as the "Type of Applicant" and it is applicable. Woman-owned small businesses are small businesses that are at least 51% owned by a woman or women, who also control and operate it.

Socially and Economically Disadvantaged:

Check this box only if both "Small Business" is selected as the "Type of Applicant" and it is applicable. Socially and economically disadvantaged status is 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

This field is required.

Select the type of application. Check only one application type. Use the following list of existing definitions to determine what application type you have. For more information, see NIH <u>Types of Applications</u>.

- **New.** Check this option when submitting an application for the first time or in accordance with other submission policies. See the NIH Guide Notice on the <u>Updated</u> Policy for Application Submission.
- **Resubmission.** Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH <u>Application Submission Policies</u>. If your application is both a "New/Revision/Renewal" and a "Resubmission," check only the "Resubmission" box.
- **Renewal.** Check this option if you are 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 if the applicant were applying for the first time.
- **Continuation.** The box for "Continuation" is used only for specific FOAs.
- **Revision.** Check this option for competing revisions and non-competing administrative supplements. For more information on competing revisions, see NIH Competing

<u>Revisions</u>. For more information on administrative supplements, see NIH <u>Administrative</u> Supplements.

Additional Instructions for Fellowship:

The applicant should generally check "New" or "Resubmission." Unless otherwise specified in the FOA, individual fellowship awards usually cannot be renewed, supplemented, or revised. Contact the awarding institute or center staff or refer to the FOA if clarification is needed.

If Revision, mark appropriate box(es).

You may select more than one.

- A. Increase Award
- B. Decrease Award
- C. Increase Duration
- D. Decrease Duration
- E. Other (specify)

If "E. Other (specify)" is selected, specify in the space provided.

The boxes for options B, C, D, and E will generally not be used and should not be selected unless specifically addressed in a particular FOA.

Is this application being submitted to other agencies? What Other Agencies?

In the field "Is this application being submitted to other agencies?" check "Yes" if one or more of the specific aims submitted in your application is also contained in a similar, identical, or essentially identical application submitted to another federal agency.

Otherwise, check "No."

If you checked "Yes," indicate the agency or agencies to which the application has been submitted.

For additional information, see the NIH Guide Notice on the <u>Updated Application Submission Policy</u>.

9. Name of Federal Agency

The "Name of Federal Agency" field is pre-populated from the opportunity package and reflects the agency from which assistance is being requested with this application.

10. Catalog of Federal Domestic Assistance Number and Title

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

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 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

This field is required.

Enter a brief descriptive title of the project.

The descriptive title is limited to 200 characters, including spaces and punctuation.

New Applications: You must have a title different than any other NIH or other PHS Agency project submitted for the same application due date with the same Project Director/Principal Investigator (PD/PI).

Resubmission or Renewal Applications: You should normally have the same title as the previous grant or application; however, if the specific aims of the project have significantly changed, choose a new title.

Revision Applications: You must have the same title as the currently funded grant.

12. Proposed Project

Start Date:

This field is required. Enter the proposed start date of the project. The start date is an estimate, and is typically at least nine months after application submission. The project period should not exceed what is allowed in the FOA.

Ending Date:

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

13. Congressional District of Applicant

Enter the Congressional District as follows: a 2-character state abbreviation, a hyphen, and a 3-character district number. Examples: CA-005 for California's 5th district, VA-008 for Virginia's 8th district.

If outside the United States, enter 00-000.

For States and U.S. Territories with only a single congressional district, enter "001" for the district number.

For jurisdictions with no representative, enter "099."

For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098 or PR-098.

If you do not know your Congressional District: Go to The United States House of Representatives website and search for your Congressional District by entering your ZIP+4. If you do not know your ZIP+4, look it up on the USPS Look Up Zip Code website.

14. Project Director/Principal Investigator Contact Information

This information is for the PD/PI. The PD/PI is the individual responsible for the overall scientific and technical direction of the project.

In the eRA Commons profile, the person listed here in "14. Project Director/Principal Investigator Contact Information" must be affiliated with the applicant organization entered in "5. Applicant

Information." If you are proposing research at an institute other than the one you are currently at, do not create a separate Commons account with the proposed applicant organization. For additional information on creating affiliations for users in the eRA Commons, see eRA Account Management System's Online Help.

If submitting an application reflecting multiple PD/PIs, the individual listed here as the Contact PD/PI in "14. Project Director/Principal Investigator Contact Information" will be the first PD/PI listed in F.240 - R&R Senior/Key Person Profile (Expanded) Form.

See <u>F.240 - R&R Senior/Key Person Profile (Expanded) Form</u> for additional instructions for multiple PD/PIs. To avoid potential errors and delays in processing, ensure that the information provided in this section is identical to the PD/PI profile information contained in the eRA Commons.

Additional Instructions for Fellowship:

Provide the name of the individual fellowship applicant (considered the PD/PI for fellowship award programs). If the PD/PI is not located at the applicant organization at the time the application is submitted, the information should reflect where the fellowship applicant can be reached prior to the requested award start date. If the PD/PI is not located at the applicant organization at the time of submission, the Commons account for the PD/PI must be affiliated with the applicant organization.

If your proposed fellowship is at a different site than your current institution, the proposed sponsoring institution will be the applicant organization. You must affiliate your Commons account with the institution so that you have access to records submitted on your behalf. Do not create a separate Commons account with the proposed sponsoring institution.

Multiple PD/PIs cannot apply to fellowship applications.

Prefix:

Enter or select the prefix, if applicable, for the name of the PD/PI.

First Name:

This field is required. Enter the first (given) name of the PD/PI.

Middle Name:

Enter the middle name of the PD/PI.

Last Name:

This field is required. Enter the last (family) name of the PD/PI.

Suffix:

Enter or select the suffix, if applicable, for the PD/PI. Do not use this field to record degrees (e.g., Ph.D. or M.D.). Degrees for the PD/PI are requested separately in the R&R Senior/Key Person Profile (Expanded) Form.

Position/Title:

Enter the position/title of the PD/PI.

Organization Name:

This field is required. This field may be pre-populated from the applicant information section in this form.

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, major subdivision, or equivalent level within the organization of the PD/PI.

Street1:

This field is required. Enter first line of the street address for the PD/PI.

Street2:

Enter the second line of the street address for the PD/PI.

City:

This field is required. Enter the city for the address of the PD/PI.

County/Parish:

Enter the county/parish for the address of the PD/PI.

State:

This field is required if the PD/PI is located in the United States or its Territories. Enter the state or territory where the PD/PI is located.

Province:

If "Country" is Canada, enter the province for the PD/PI; otherwise, skip the "Province" field.

Country:

Select the country for the PD/PI.

ZIP/Postal Code:

The ZIP+4 is required if the PD/PI address is in the United States. Otherwise, the postal code is optional. Enter the ZIP+4 (nine-digit postal code) or postal code of the PD/PI.

Phone Number:

This field is required. Enter the daytime phone number for the PD/PI.

Fax Number:

Enter the fax number for the PD/PI.

E-mail:

This field is required. Enter the e-mail address for the PD/PI.

15. Estimated Project Funding

All four fields in "15. Estimated Project Funding" are required.

a. Total Federal Funds Requested

Enter the total federal funds, including Direct Costs and F&A Costs (Indirect Costs), requested for the entire project period.

Additional Instructions for Fellowship:

Applicants should refer to the NIH Research Training and Career Development website for current stipend and other budgetary levels. Enter the total amount requested for the entire period of support. This amount should include 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.

b. Total Non-Federal Funds

For applications to NIH and other PHS agencies, enter "0" in this field unless cost sharing is a requirement for the specific FOA.

c. Total Federal & Non-Federal Funds

Enter the total federal and non-federal Funds requested. The amount in this field will be the same as the amount in the "Total Federal Funds Requested" field unless the specific FOA indicates that cost sharing is a requirement.

d. Estimated Program Income

Indicate any program income estimated for this project, if applicable.

Additional Instructions for Fellowship:

Enter "0," as the "Estimated Program Income" does not apply to fellowship applications.

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

Applicants should check "No, Program is not covered by E.O. 12372."

17. Certification

This field is required.

The list of NIH and other PHS agencies Certifications, Assurances, and other Policies is found in the Supplemental Instructions, Part III, Section 2: Assurances and Certifications.

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 and/or civil 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.

Check "I agree" to provide the required certifications and assurances.

18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation

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

If unable to certify compliance with the Certification in the "17. Certification" section above, attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, <u>Disclosure</u> of <u>Lobbying Activities</u>) or other documents in this item.

For more information:

See <u>Supplemental Instructions</u>, Part III, Section 2 Assurances and Certifications, and the NIH Lobbying Guidance for Grantee Activities page.

19. Authorized Representative

The authorized representative is equivalent to the individual with the organizational authority to sign for an application. This individual is otherwise known as the authorized organization representative (AOR) in Grants.gov or the signing official (SO) in eRA Commons.

Prefix:

Enter or select the prefix, if applicable, for the name of the AOR/SO.

First Name:

This field is required. Enter the first (given) name of the AOR/SO

Middle Name:

Enter the middle name of the AOR/SO.

Last Name:

This field is required. Enter the last (family) name of the AOR/SO.

Suffix:

Enter or select the suffix, if applicable, for the AOR/SO.

Position/Title:

This field is required. Enter the position/title of the name of the AOR/SO.

Organization Name:

This field is required. Enter the name of the organization for the AOR/SO.

Department:

Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization for the AOR/SO.

Division:

Enter the name of the primary organizational division, office, major subdivision, or equivalent level within the organization for the AOR/SO.

Street1:

This field is required. Enter the first line of the street address for the AOR/SO.

Street2:

Enter the second line of the street address for the AOR/SO.

City:

This field is required. Enter the city for the address of the AOR/SO.

County/Parish:

Enter the county/parish for the address of the AOR/SO.

State:

This field is required if the AOR/SO is located in the United States or its Territories. Enter the state or territory where the AOR/SO is located.

Province:

If "Country" is Canada, enter the province for the AOR/SO; otherwise, skip the "Province" field.

Country:

Select the country for the address of the AOR/SO.

ZIP/Postal Code:

The ZIP+4 is required if the AOR/SO is in the United States. Otherwise, the postal code is optional Enter the ZIP+4 (nine-digit postal code) or postal code of the AOR/SO.

Phone Number:

This field is required. Enter the daytime phone number for the AOR/SO.

Fax Number:

Enter the fax number for the AOR/SO.

Email:

This field is required. Enter the e-mail address for the AOR/SO.

Signature of Authorized Representative:

Grants.gov will record the electronic signature for the AOR/SO who submits the application.

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.

Date Signed:

Grants.gov will generate this date upon application submission.

20. Pre-application

Unless specifically noted in a FOA, NIH and other PHS agencies do not use pre-applications. The "Pre-application" attachment field should not be used for any other purpose.

If permitted by your FOA, attach this information as a PDF.

21. Cover Letter Attachment

The cover letter is for internal use only and will not be shared with peer reviewers.

Who must complete the "Cover Letter Attachment:"

Refer to the "content" list below for items that are permitted, as well as for specific situations in which a cover letter must be included.

A cover Letter must not be included with post-award submissions, such as administrative supplements, change of grantee institution, or successor-in-interest.

Format:

Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the FOA and/or these instructions.

Attach the cover letter in the correct location, specifically verifying that the cover letter has not been uploaded to the "20. Pre-application" field which is directly above the "21. Cover Letter Attachment" field. This will ensure the cover letter attachment is kept separate from the assembled application in the eRA Commons and made available only to appropriate staff.

Content:

The letter should contain any of the following information, as applicable:

- 1. Application title.
- 2. Title of FOA (PA or RFA).
- 3. For late applications (see Late Application policy on NIH's <u>Application Submission</u> Policies) include specific information about the timing and nature of the delay.
- 4. For changed/corrected applications submitted after the due date, a cover letter is required, and it must explain the reason for late submission of the changed/corrected applications. If you already submitted a cover letter with a previous submission and are now submitting a late change/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.
- 5. Explanation of any subaward budget components that are not active for all budget periods of the proposed grant (see F.310 R&R Subaward Budget Attachment(s) Form).
- 6. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications that request \$500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or

- U13), etc. It is recommended that you include the official communication from an NIH official as part of your cover letter attachment.
- 7. When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, the video will not be accepted. See NIH Guide Notice on the Interim Guidance for Videos Submitted as NIH Application Materials for additional information.
- 8. Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy (see the NIH Guide Notices on the Implementation of the NIH Genomic Data Sharing Policy and Reminder about the Implementation of the Genomic Data Sharing Policy).

Additional Instructions for Fellowship:

Individual fellowship applicants must include a cover letter that contains a list of referees (including name, departmental affiliation, and institution).

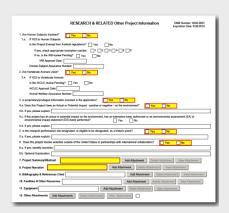
F.220 - R&R Other Project Information Form

The R&R Other Project Information Form is used for all grant applications. This form includes questions on the use of human subjects, vertebrate animals, and environmental impact. This form also has fields to upload an abstract, project narrative, references, information on facilities, and equipment lists.



Quick Links

- 1. Are Human Subjects Involved?
- 1a. If YES to Human Subjects
- 2. Are Vertebrate Animals Used?
- 2a. If YES to Vertebrate Animals
- 3. <u>Is proprietary/privileged information included in the application?</u>
- 4. Environmental Questions
- 5. <u>Is the research performance site designated, or</u> eligible to be designated, as a historic place? Yes/No
- 6. Does this project involve activities outside of the United States or partnerships with international Collaborators?
- 7. Project Summary/Abstract
- 8. Project Narrative
- 9. Bibliography & References Cited
- 10. Facilities & Other Resources
- 11. Equipment
- 12. Other Attachments



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Additional Instructions for Fellowship:

This R&R Other Project Information Form should be completed in consultation with the sponsor and administrative officials at the sponsoring institution.

1. Are Human Subjects Involved?

This field is required.

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, or if activities involving human subjects are anticipated within the period of award but plans are indefinite.

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 the "1. Are Human Subjects Involved" section.

Need help determining whether your application includes human subjects? Check out the NIH Research Involving Human Subjects website for information, including an Infopath Questionnaire designed to walk applicants through the decision process.

Note on the use of human specimens or data: Applications involving the use of human specimens or data may or may not be considered to be research involving human subjects, depending on the details of the materials to be used. Applications that involve the use of human materials that check "No" for human subjects involvement must provide a clear justification about why this use does not constitute human subjects research. For more detail, refer to Supplemental Instructions, Part II.

Additional Instructions for Fellowship:

In many instances, the fellow 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 Fellow does not substantially modify the research.

If you have answered "Yes" to the "Are Human Subjects Involved?" question, you must also complete the Protection of Human Subjects attachment in <u>F.430 - PHS</u> Fellowship Supplemental Form, Protection of Human Subjects.

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? Yes/No

If the project is exempt from federal regulations, check "Yes" and check the appropriate exemption number.

Human subjects research should only be designated as exempt if all of the proposed research projects in an application meet the criteria for exemption.

If the project is not exempt from federal regulations, check "No."

For more information, see the NIH's Exempt Human Subjects Research infographic.

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

If you selected "Yes" to "Is the Project Exempt from Federal Regulations," select the appropriate exemption number.

The six categories of research that qualify for exemption are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at 45 CFR 46.

Need help determining the appropriate exemption number? Refer to NIH's Research Involving Human Subjects Frequently Asked Questions.

The Office of Human Research Protections (OHRP) guidance states that appropriate use of exemptions described in 45 CFR 46 should be determined by an authority independent from the

investigators (for more information, see OHRP's Frequently Asked Questions). Institutions often designate their Institutional Review Board (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.

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

If IRB review is pending, check "Yes."

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not started by the time of submission.

If IRB review is not pending (e.g., if the review is complete), check "No."

IRB Approval Date:

Enter the latest IRB approval date (if available). Leave blank if IRB approval is pending.

An IRB approval date is not required at the time of submission when IRB review is pending. This may be requested later in the pre-award cycle as a Just-In-Time requirement. See <u>Supplemental Instructions</u>, Part III, Section 1.7: Just-in-Time Policy for more information.

Human Subject Assurance Number:

Enter the approved Federalwide Assurance (FWA) number that the applicant has on file with OHRP. Enter the 8-digit number. Do not enter "FWA" before the number.

Enter "None" if the applicant organization does not have an approved FWA on file with OHRP. In this case, the applicant organization, by the signature in the Certification section on the <u>F.200 - SF424 (R&R) Form</u>, is declaring that it will comply with <u>45 CFR 46</u> and proceed to obtain a FWA (see <u>Office for Human Research Protections</u> website). Do not enter the FWA number of any collaborating institution.

Additional Instructions for Fellowship:

If research proposed in the fellowship application has been previously reviewed and approved by an IRB and is covered by an approved FWA, provide the FWA number and the latest IRB approval date for the proposed activities. The latest IRB approval date must be within one year of the application due date.

2. Are Vertebrate Animals Used?

This field is required.

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check "Yes." Otherwise, check "No" and skip the rest of the "2. Are Vertebrate Animals Used?" section.

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."

Additional Instructions for Fellowship:

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.

If you have answered "Yes" to the "Are Vertebrate Animals Used?" question, you must also provide an explanation and anticipated timing of animal use in <u>F.430 - PHS Fellowship Supplemental Form, Vertebrate Animals</u>. This attachment must be submitted and reviewed prior to the involvement of animals in any research studies.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

If an Institutional Animal Care and Use Committee (IACUC) review is pending, check "Yes."

Applicants should check "Yes" to the "Is the IACUC review Pending?" question even if the IACUC review/approval process has not started by the time of submission.

If IACUC review is not pending (e.g. if the review is complete), check "No."

IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if IACUC approval is pending. IACUC approval must have been granted within three years of the application submission date to be valid.

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 Supplemental Instructions, Part III, Section 1.7: Just-in-Time Policy.

Animal Welfare Assurance Number

Enter the federally approved assurance number, if available.

Enter "None" if the applicant organization does not have an Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance.

To determine whether the applicant organization holds an Animal Welfare Assurance with an associated number, see the lists of <u>Domestic</u> and <u>Foreign</u> Assured institutions. Also note the NIH Guide Notice on the <u>Animal Welfare Assurance Numbering System</u>, effective July 2016. **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 number, the authorized organization representative's signature on the application constitutes declaration

that the applicant organization will submit an Animal Welfare Assurance when requested by OI AW.

If the animal work will be conducted at an institution with an Animal Welfare Assurance and the applicant organization does not have the following:

- an animal care and use program;
- facilities to house animals and conduct research on site; and
- IACUC;

then, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

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

This field is required.

Patentable ideas; trade secrets; or privileged, confidential commercial, or financial information 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 statement 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 statement can be included at the top of each page as applicable.

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 NIH and other PHS agencies 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 5). Additionally, if an applicant fails to identify proprietary information at the time of submission as instructed here, a significant substantive justification will be required to withhold the information if requested under FOIA.

4. Environmental Questions

Question 4 pertains to the environmental impact of the proposed research.

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment?

This field is required.

Indicate whether or not this project has an actual or potential impact on the environment.

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" 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 scenarios, check "Yes."

- 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.b. If yes, please explain:

If you answered "Yes" to Question 4.a., you must provide an explanation here as to the actual or potential impact of the proposed research 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 environmental impact statement (EIS) been performed? Yes/No.

This field is required if you answered "Yes" to Question 4.a. Check "Yes" or "No."

4.d. If yes, please explain:

Enter additional details about the EA or EIS here.

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

This field is required.

If any research performance site is designated, or eligible to be designated, as a historic place, check the "Yes" box. Otherwise, check "No."

5.a. If yes, please explain:

If you checked "Yes" to indicate that 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?

This field is required.

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check "Yes" or "No."

Applicants to NIH and other PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component. See NIH Glossary for a definition of a foreign component.

If you have checked "Yes" to Question 6, you must include a "Foreign Justification" attachment in Field 12, Other Attachments. Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting. In the body of the text, begin the section with a heading indicating "Foreign Justification" and name the file "Foreign Justification."

Additional Instructions for Fellowship:

If you have checked "Yes" to Question 6, and are including a "Foreign Justification" attachment, you should include in your justification a description of how the mentor at the foreign site will contribute the scientific advantages of the foreign training experience as compared to the training available domestically.

6.a. If yes, identify countries:

This field is required if you answered "Yes" to Question 6. Enter the countries with which international cooperative activities are planned.

6.b. Optional Explanation:

This field is optional. Enter an explanation for involvement with outside entities.

7. Project Summary/Abstract

The "Project Summary/Abstract" attachment is required.

The project summary is a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application). This section should be informative to other persons working in the same or related fields and understandable to a scientifically literate reader. Avoid both descriptions of past accomplishments and the use of the first person. Please be concise.

Format:

This section is limited to 30 lines of text, and must follow the required <u>font and margin</u> <u>specifications</u>. A summary which exceeds this length will be flagged as an error by the Agency upon submission. You will need to take corrective action before the application can be accepted.

Attach this information as a PDF file. See the Format Attachments page.

Content:

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 the research design and methods for achieving the stated goals. Be sure that the project summary reflects the key focus of the proposed project so that the application can be appropriately categorized.

Do not include proprietary, confidential information or trade secrets in the project summary. If the application is funded, the project summary will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT) and will become public information.

Note that the "Project Summary/Abstract" attachment is not same as the "Research Strategy" attachment.

8. Project Narrative

The "Project Narrative" attachment is required.

Content:

Describe the relevance of this research to public health in, at most, three sentences. For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.

9. Bibliography & References Cited

Who must complete the "Bibliography & References Cited" attachment:

The "Bibliography & References Cited" attachment is required unless otherwise noted in the FOA.

Format:

Attach this information as a PDF file. See the Format Attachments page.

Content:

See the following instructions for which references to include in the "Bibliography and References Cited" attachment.

Additional Instructions for Fellowship:

The "Bibliography & References Cited" attachment should include any references cited in F.430 - PHS Fellowship Supplemental 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." NIH maintains a list of such journals.

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.



Beginning with application due dates on or after May 25, 2017, you are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

10. Facilities & Other Resources

Format:

The "Facilities & Other Resources" attachment is required unless otherwise specified in the FOA.

Content:

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 from unique subject populations or how studies 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 and any other potentially dangerous substances. **Note: Information about select agents must be described in the Research Plan, Select Agent Research.**

For early stage investigators (ESIs), describe institutional investment in the success of the investigator. See NIH's <u>New and Early Stage Investigator Policies</u>. Your description may include the following elements:

- resources for classes, travel, or training;
- collegial support, such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups;
- logistical support, such as administrative management and oversight and best practices training;
- financial support, such as protected time for research with salary support.

Additional Instructions for Fellowship:

Include a detailed description of the institutional facilities and resources available to the fellowship applicant. The information provided is of major importance in establishing the feasibility of the goals of the fellowship training plan.

11. Equipment

The "Equipment" attachment is required.

Format:

Attach this information as a PDF file.

Content

List major items of equipment already available for this project and, if appropriate, identify the equipment's location and pertinent capabilities.

12. Other Attachments

Attach a file to provide additional information only in accordance with the FOA and/or agency-specific instructions.

If applicable, attach a "Foreign Justification" here. (See Question 6 above).

Additional Instructions for Fellowship:

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 letter should avoid revealing sensitive personal information, such as the candidate's specific racial/ethnic background or type of disability. The certification letter must be on institutional letterhead and scanned so that an institutional official signature is visible.

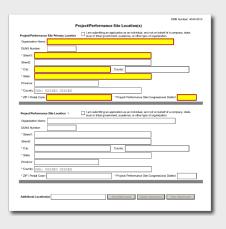
F.230 - Project/Performance Site Location(s) Form

The Project/Performance Site Location(s) Form is used for all grant applications. It is used to report the primary location and any other locations at which the project will be performed.

View larger image

Quick Links

- Project/Performance Site Primary Location
- Project/Performance Site Location 1
- Additional Locations



Using the Project/Performance Site Locations(s) Form:

This form allows for the collection of multiple performance sites. If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the "Additional Locations" section.

Project/Performance Site Primary Location

Generally, the primary location should be that of the applicant organization or identified as offsite in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the budget form of the application.

Provide an explanation of resources available from each project/performance site on the "Facilities and Resources" attachment of the F.220 - R&R Other Project Information Form.

If the proposed project involves human subjects or live vertebrate animals, it is up to the applicant organization to ensure that all sites meet certain criteria:

Human Subjects: If a project/performance site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the project/performance site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR 46 and other NIH human subject related policies described in the Supplemental Instructions, Part II and in the NIH Grants Policy Statement.

Vertebrate Animals: For research involving live vertebrate animals, the applicant organization must ensure that all project/performance sites hold an Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance. If the animal work will be conducted at an institution with an Animal Welfare Assurance and the applicant organization does not have the following:

- an animal care and use program;
- facilities to house animals and conduct research on site; and
- an IACUC;

then applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

Additional Instructions for Fellowship:

One of the sites indicated must be the sponsoring organization, and generally, the sponsoring organization is the primary location. 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 or foreign sites, list them all in the fields provided for Location 1, and additional locations, as necessary.

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 <u>F.220 - R&R</u> Other Project Information Form, Facilities and Resources.

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 the "12. Other Attachments" section in F.220 - R&R Other Project Information Form.

"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":

Do not check the box for "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" unless otherwise specified by the FOA.

Organization Name:

This field is required. Enter the organization name of the primary site where the work will be performed.

DUNS Number:

This field is required for the primary performance site.

Enter the DUNS or DUNS+4 number associated with the organization where the project will be performed.

Street1:

This field is required. Enter the first line of the street address of the primary performance site location.

Street2:

Enter the second line of the street address of the primary performance site location.

City:

This field is required. Enter the city for the address of the primary performance site location.

County:

Enter the county of the primary performance site location.

State:

This field is required if the site is located in the United States or its Territories. Enter the state or territory where the primary performance site is located.

Province:

If "Country" is Canada, enter the province for the primary performance site; otherwise, skip the "Province" field.

Country:

This field is required. Select the country of the address for the primary performance site location.

ZIP/Postal Code:

The ZIP+4 is required if the primary performance site location is in the United States. Otherwise, the postal code is optional. Enter the ZIP+4 (nine-digit postal code) or postal code of the primary performance site.

Project/Performance Site Congressional District:

Enter the Congressional District as follows: a 2-character state abbreviation, a hyphen, and a 3-character district number. Examples: CA-005 for California's 5th district, VA-008 for Virginia's 8th district.

It is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application.

If the program/project is outside the United States, enter 00-000.

For States and U.S. territories with only a single congressional district, enter "001" for the district number.

For jurisdictions with no representative, enter "099."

For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098 or PR-098.

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 you do not know the Congressional District: Go to the <u>United States House of</u>

<u>Representatives</u> website and search for the Congressional District by entering the ZIP+4. If you do not know the ZIP+4, look it up on the <u>USPS Look Up Zip Code</u> website.

Project/Performance Site Location 1

Use this "Project/Performance Site Location 1" block to provide information on performance sites in addition to the Primary Performance Site listed above, if applicable. Include any VA facilities and foreign sites.

Organization Name:

Enter the organization name of the performance site location.

DUNS Number:

Enter the DUNS or DUNS+4 number associated with the performance site.

Street1:

This field is required. Enter first line of the street address of the performance site location.

Street2:

Enter the second line of the street address of the performance site location.

City:

This field is required. Enter the city for the address of the performance site location.

County:

Enter the county of the performance site location.

State:

This field is required if the project performance site is located in the United States or its Territories. Enter the state or territory where the performance site is located.

Province:

If "Country" is Canada, enter the province for the performance site; otherwise, skip the "Province" field.

Country:

This field is required. Select the country of the performance site location.

ZIP/Postal Code:

The ZIP+4 is required if the performance site location is in the United States. Otherwise, the postal code is optional. Enter the ZIP+4 (nine-digit postal code) of the performance site location.

Project/Performance Site Congressional District:

Enter the Congressional District as follows: a 2-character state abbreviation, a hyphen, and a 3-character district number. Examples: CA-005 for California's 5th district, VA-008 for Virginia's 8th district.

If the program/project is outside the United States, enter 00-000.

For States and U.S. territories with only a single congressional district enter "001" for the district number.

For jurisdictions with no representative, enter "099."

For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098 or PR-098.

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 you do not know the Congressional District: Go to the <u>United States House of</u>

<u>Representatives</u> website and search for your Congressional District by entering your ZIP+4. If you do not know the ZIP+4 look it up on the <u>USPS Look Up Zip Code</u> website.

Additional Locations

If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the "Additional Locations" section.

A format page for Additional Performance Sites can be found on NIH's <u>Additional Performance</u> Site Format Page.

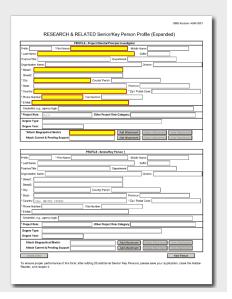
F.240 - R&R Senior/Key Person Profile (Expanded) Form

The R&R Senior/Key Person Profile (Expanded) Form is used for all grant applications, and allows the collection of data for all senior/key persons associated with the project. Some information for the PD/PI may be prepopulated from the SF424 (R&R) form. See instructions in F.200 - SF 424 (R&R) Form if these fields are empty.



Quick Links

- Profile Project Director/Principal Investigator
- Instructions for a Biographical Sketch
- Profile Senior/Key Person 1
- Additional Senior/Key Person Profile(s)



Using the R&R Senior/Key Person Profile (Expanded) Form

This form allows for the data collection for a PD/PI and up to 99 other senior/key individuals (including any multi-PD/PIs). After the first 100 individuals have been entered, use the "Additional Senior/Key Person Profiles Format Page" to attach any remaining data.

To ensure proper performance of this form, save your work frequently.

Who qualifies as a Senior/Key Person?

Unless otherwise specified in a FOA, 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 in this "Senior/Key Person Profile (Expanded)" Form if they meet this definition.

List individuals that meet the definition of senior/key regardless of what organization they work for.

Profile - Project Director/Principal Investigator

Enter data in this "Profile – Project Director/Principal Investigator" section for the Project Director/Principal Investigator (PD/PI).

The PD/PI must have an eRA Commons account with the PI role, and the account must be affiliated with the applicant organization. If you are proposing research at an institute other than the one you are currently at, do not create a separate Commons account with the proposed applicant organization. For information on eRA Commons account administration, see the eRA Account Management System's Online Help.

Special Instructions for Multiple PD/PI: When submitting an application involving multiple PD/PIs, list the "Contact" PD/PI in this field. List all additional PD/PIs in the Senior/Key Person section(s) below.

Additional Instructions for Fellowship:

For all fellowship applications, the applicant is considered the PD/PI. Therefore, the applicant must have an eRA Commons account with the PI role, and the account must be affiliated with the applicant organization. For additional information on eRA Commons account administration, see the eRA Account Management
System's Online Help.

If your proposed fellowship is at a different site than your current institution, the proposed sponsoring institution will be the applicant organization. You must affiliate your Commons account with the institution so that you have access to records submitted on your behalf. Do not create a separate Commons account with the proposed sponsoring institution.

Note that "multiple PD/PIs" are not applicable to fellowship applications, so do not use the PD/PI role for any other senior/key personnel.

Prefix:

This field may be pre-populated from the SF 424 (R&R) and reflects the prefix, if applicable, for the name of the PD/PI.

First Name:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the first (given) name of the PD/PI.

Middle Name:

This field may be pre-populated from the SF 424 (R&R) and reflects the middle name of the PD/PI.

Last Name:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the last (family) name of the PD/PI.

Suffix:

This field may be pre-populated from the SF 424 (R&R) and reflects the suffix for the name of the PD/PI.

Position/Title:

This field may be pre-populated from the SF 424 (R&R) and reflects the position/title of the PD/PI.

Department:

This field may be pre-populated from the SF 424 (R&R) and reflects the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.

Organization Name:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the name of the organization of the PD/PI.

Division:

This field may be pre-populated from the SF 424 (R&R) and reflects the name of the primary organizational division, office, major subdivision, or equivalent level within the organization of the PD/PI.

Street1:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the first line of the street address for the PD/PI.

Street2:

This field may be pre-populated from the SF 424 (R&R) and reflects the second line of the street address for the PD/PI.

City:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the city for the address of the PD/PI.

County/Parish:

This field may be pre-populated from the SF 424 (R&R) and reflects the county/parish for the address of the PD/PI.

State:

This field is required if the PD/PI is located in the United States or its Territories. This field may be pre-populated from the SF 424 (R&R) and reflects the state or territory in which the PD/PI is located.

Province:

If "Country" is Canada, enter the province for the PD/PI; otherwise, skip the "Province" field. This field may be pre-populated from the SF 424 (R&R) and reflects the province in which the PD/PI is located.

Country:

This field may be pre-populated from the SF 424 (R&R) and reflects the country for the address of the PD/PI.

ZIP/Postal Code:

The ZIP+4 is required if the PD/PI address is in the United States. Otherwise, the postal code is optional. This field may be pre-populated from the SF 424 (R&R) and reflects the postal code of the address of the PD/PI.

Phone Number:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the daytime phone number for the PD/PI.

Fax Number:

This field may be pre-populated from the SF 424 (R&R) and reflects the fax number for the PD/PI.

E-mail:

This field is required. This field may be pre-populated from the SF 424 (R&R) and reflects the email address for the PD/PI.

Credential, e.g., agency login:

This field is required. Enter the assigned eRA Commons username for the project's PD/PI. The eRA Commons username must hold the PI role and be affiliated with the applicant organization. Applications will not pass agency validation requirements without a valid eRA Commons username.

Special Instructions for Multiple PD/PI: The Commons username must be provided for all individuals assigned the Project Role of PD/PI on the application.

Project Role:

Enter "PD/PI" for the Project Role for the PD/PI.

Other Project Role Category:

Skip the "Other Project Role Category" field, as no other role can be added to the PD/PI role.

Degree Type:

Enter the highest academic or professional degree or other credentials (e.g., R.N.).

Degree Year:

Enter the year the highest degree or other credential was obtained.

Attach Biographical Sketch

Provide a biographical sketch for each PD/PI. See instructions <u>below</u> on how to complete a biographical sketch.

Attach Current & Pending Support:

Do not use this attachment upload for NIH and other PHS agency submissions unless otherwise specified in the FOA.

While this information is not required at the time of application submission, it may be requested later in the pre-award cycle. If and when this occurs, refer to <u>Supplemental Instructions</u>, <u>Part III</u>, <u>Section 1.8: Other Support</u>.

Instructions for a Biographical Sketch

These instructions apply to Research (R), Career Development (K), Training (T), Fellowship (F), Multi-project (M), and SBIR/STTR (B).

Who must complete the "Biographical Sketch" section:

All senior/key personnel and <u>other significant contributors (OSCs)</u> must include biographical sketches (biosketches).

Format:

Use the sample format on the <u>Biographical Sketch Format Page</u> to prepare this section for all grant applications.

Figures, tables, or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).

The biosketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.

Attach this information as a PDF file. See the Format Attachments page.

Content:

Note that the instructions here follow the format of Biographical Sketch Format Page.

Name:

Fill in the name of the senior/key person or other significant contributor in the "Name" field of the Biosketch Format Page.

eRA Commons User Name:

If the individual is registered in the <u>eRA Commons</u>, fill in the eRA Commons User Name in the "eRA Commons User Name" field of the Biosketch Format Page.

The "eRA Commons User Name" field is required for the PD/PI (including career development and fellowship applicants), primary sponsors of fellowship applicants, all mentors of candidates for mentored career development awards, and candidates for diversity and reentry research supplements.

The "eRA Commons User Name" field is optional for other project personnel.

The eRA Commons User Name should match the information provided in the <u>Credential</u> field of the R&R Senior/Key Person Profile (Expanded) Form in your grant application.

Position Title:

Fill in the position title of the senior/key person or other significant contributor in the "Position Title" field of the Biosketch Format Page.

Education/Training

Complete the education block. Begin with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately.

For each entry provide:

- the name and location of the institution
- the degree received (if applicable)
- the month and year of end date (or expected end date). For fellowship applicants only, also include the month and year of start date.
- the field of study (for residency entries, the field of study should reflect the area of residency training)

Following the education block, complete Sections A-D of the biographical sketch.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. 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/or your past performance in this or related fields.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other

presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.



Beginning with application due dates on or after May 25, 2017, you are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

Note the following additional instructions for ALL applicants/candidates:

- If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this "A. Personal Statement" section.
- Indicate whether you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application.
- Figures, tables, or graphics are not allowed.

Note the following instructions for specific subsets of applicants/candidates:

- For institutional research training, institutional career development, or research education grant applications, faculty who are not senior/key persons are encouraged, but not required, to complete the "A. Personal Statement" section.
- Applicants for dissertation research awards should, in addition to addressing the points noted above, also include a description of their career goals, their intended career trajectory, and their interest in the specific areas of research designated in the FOA.
- Candidates for research supplements to promote diversity in health-related research should, in addition to addressing the points noted above, also include a description of their general scientific achievements and/or interests, specific research objectives, and career goals. Indicate any current source(s) of educational funding.

B. Positions and Honors

List in chronological order the positions you've held that are relevant to this application, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

C. Contributions to Science

Who should complete the "Contributions to Science" section:

All senior/key persons should complete the "Contributions to Science" section except candidates for research supplements to promote diversity in health-related research who are high school

students, undergraduates, and post-baccalaureates.

Format:

Briefly describe up to five of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations.

While all applicants may describe up to five contributions, graduate students and postdoctorates may wish to consider highlighting two or three they consider most significant.

Content:

For each contribution, indicate the following:

- 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;
- your specific role in the described work.

For each contribution, you may cite up to four publications or research products that are relevant to the contribution. If you are not the author of the product, indicate what your role or contribution was. Note that while you may mention manuscripts that have not yet been accepted for publication as part of your contribution, you may cite only published papers to support each contribution. Research products can include audio or video products (see the NIH Guide Notice on Guidance for Videos Submitted as NIH Application Materials); conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

Beginning with application due dates on or after May 25, 2017, you are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required.

Descriptions of contributions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication. These contributions do not have to be related to the project proposed in this application.

D. Additional Information: Research Support and/or Scholastic Performance

Note the following instructions for specific subsets of applicants/candidates:

- High school students are *not* required to complete Section D. Additional Information: Research Support and/or Scholastic Performance.
- Career development award applicants should complete the "Research Support" section but skip the "Scholastic Performance" section.
- Generally, the following types of applicants can skip the "Research Support" section and must complete **only** the "Scholastic Performance" section. However, when these applicants also have Research Support, they may complete both sections.
 - applicants for predoctoral and postdoctoral fellowships,

- applicants to dissertation research grants,
- candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels.

Research Support

These instructions apply to all applicants who are completing the "Research Support" section.

List ongoing and completed research projects from the past three years that you want to draw attention to. Briefly indicate the overall goals of the projects and your responsibilities. Do not include the number of person months or direct costs.

Do not confuse "Research Support" with "Other Support." Other Support information is not collected at the time of application submission.

- **Research Support:** 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 your qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.
- Other Support: NIH staff may request complete and up-to-date "other support" information from you as part of Just-in-Time information collection.

Scholastic Performance

Predoctoral applicants/candidates (including undergraduates and post-baccalaureates): List by institution and year **all** undergraduate and graduate courses, with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

Postdoctoral applicants: List by institution and year all undergraduate courses and graduate scientific and/or professional courses relevant to the training sought under this award, with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

Profile - Senior/Key Person 1

Enter data in this "Profile – Senior/Key Person 1" section to provide information on a senior/key person (other than the PD/PI listed above), if applicable.

Format:

List all senior/key person profiles, followed by other significant contributors (OSC) profiles.

Content – Who to include in the "Profile – Senior/Key Person" section:

Senior/Key Persons: Fill in a separate "Profile – Senior/Key Person" block for each <u>senior/key personnel</u>. Those with a postdoctoral role should be included if they meet the NIH Glossary definition of <u>senior/key personnel</u>. A biosketch is required for all senior/key persons.

Other Significant Contributors: Also use the "Profile – Senior/Key Person" section to list any other significant contributors (OSCs). Consultants should be included if they meet the NIH Glossary definition of OSC. OSCs should be listed **after** all other senior/key persons.

A biosketch is required for all OSCs. The biosketch should highlight the OSC's accomplishments as a scientist. Reviewers assess these pages during peer review. For more information on review criteria, see the Review Criteria at a Glance document. Although Other Support information is required as a just-in-time submission, Other Support information will NOT be required or accepted for OSCs since considerations of overlap do not apply to these individuals.

Should the level of involvement increase for an individual listed as an OSC, thus requiring measurable effort on the award, the individual must be redesignated as "senior/key personnel." This change must be made before any compensation is charged to the project.

For more information:

For more information, refer to these NIH Senior/Key Personnel Frequently Asked Questions.

Additional Instructions for Fellowship:

Who to include in the "Profile – Senior/Key Person" information section:

Fellowship awards require a primary sponsor, and there may also be co-sponsor(s), consultants, and contributors. All individuals who have committed to contribute to the scientific development and execution of the project, including sponsor and co-sponsors, should be identified as senior/key personnel, even if they are not committing any specified measurable effort to the proposed project, and must provide a Commons username.

In addition to involving sponsors and co-sponsors, fellowship applications may also involve collaborators, consultants, advisory committee members, and contributors, all of whom should also be identified as senior/key personnel if they contribute in a substantive, meaningful way to the project, regardless of effort. In determining which individuals to identify as "Senior/Key," applicants may wish to keep in mind that those listed as senior/key personnel on the application should not be asked to provide reference letters, as such letters are expected to be from individuals not directly involved in the application. For more information, see NIH's Reference Letters page

Prefix:

Enter or select the prefix, if applicable, for the name of the senior/key person.

First Name:

This field is required. Enter the first (given) name of the senior/key person.

Middle Name:

Enter the middle name of the senior/key person.

Last Name:

This field is required. Enter the last (family) name of the senior/key person.

Suffix:

Enter or select the suffix, if applicable, for the senior/key person.

Position/Title:

Enter the position/title of the senior/key person.

Department:

Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the senior/key person.

Organization Name:

This field is required. Enter the name of the organization of the senior/key person.

Division:

Enter the name of the primary organizational division, office, major subdivision, or equivalent level within the organization of the senior/key person.

Street1:

This field is required. Enter the first line of the street address for the senior/key person.

Street2:

Enter the second line of the street address for the senior/key person.

City:

This field is required. Enter the city for the address of the senior/key person.

County/Parish:

Enter the county/parish for the address of the senior/key person.

State:

This field is required if the Senior/Key person is located in the United States or its Territories. Enter the state or territory where the senior/key person is located.

Province:

If "Country" is Canada, enter the province for the senior/key person; otherwise, skip the "Province" field.

Country:

This field is required. Select the country for the address of the senior/key Person.

ZIP/Postal Code:

The ZIP+4 is required if the Senior/Key Person is in the United States. Otherwise, the postal code is optional. Enter the ZIP+4 (nine-digit postal code) or postal code of the senior/key person.

Phone Number:

This field is required. Enter the daytime phone number for the senior/key person.

Fax Number:

Enter the fax number for the senior/key person.

E-mail:

This field is required. Enter the e-mail address for the senior/key person.

Credential, e.g., agency login:

If you have an established eRA Commons personal profile, enter the senior/key person's username. If you do not have an eRA Commons personal profile, skip the "Credential" field.

Additional Instructions for Fellowship:

For senior/key person who are the primary sponsor, an eRA Commons username must be provided in the "Credential" field. For more information, see the NIH Guide Notice on eRA Commons Username Requirements for Sponsors of Fellowship Applications.

Project Role:

Select a project role. Use "Other (Specify)" if the desired category is not available.

Special Instructions for Multiple PD/PI: All PD/PIs must be assigned the "PD/PI" role, even those at organizations other than the applicant organization. The role of "Co-PD/PI" is not currently used by NIH or other PHS agencies to designate a multiple PD/PI application. In order to avoid confusion, do not use the role of "Co-PD/PI."

Note on OSCs: For OSCs, enter "Other (Specify)" for the "Project Role" field, and enter "Other Significant Contributor" in the "Other Project Role Category" field.

Additional Instructions for Fellowship:

For sponsors, co-sponsors, and doctoral dissertation advisors, enter "Other (Specify)" for the "Project Role" field, and enter the appropriate role (e.g., Sponsor) in the "Other Project Role Category" field.

"Multiple PD/PIs" are not applicable to fellowship applications. The PD/PI role must be used only for the applicant and not for any other senior/key personnel.

Other Project Role Category:

Complete this field (e.g., Engineer, Chemist, Sponsor, Mentor) if you selected "Other Professional" or "Other (Specify)" in the "Project Role" field.

Degree Type:

Enter the highest academic or professional degree or other credentials (e.g., R.N.).

Degree Year:

Enter the year the highest degree or other credential was obtained.

Attach Biographical Sketch:

Provide a biographical sketch for each senior/key person and each OSC. See instructions <u>above</u> on how to complete a biographical sketch.

Attach Current & Pending Support:

Do not use the "Current & Pending Support" attachment upload for NIH or other PHS agency submissions unless otherwise specified in the FOA.

While this information is not required at the time of application submission, it may be requested later in the pre-award cycle. If and when this occurs, refer to Supplemental Instructions, Part III, Section 1.8: Other Support for instructions and use the Current and Pending Support Format Page.

Additional Senior/Key Person Profile(s)

If you need to add more Senior/Key Person Profiles than the form allows, enter the information in a separate file and attach it as a PDF.

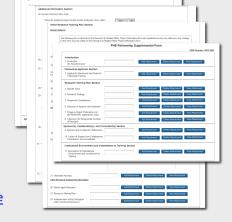
A format page for Additional Senior/Key Person Profiles can be found at NIH's <u>Additional Senior/Key Person Form</u> page.

F.430 - PHS Fellowship Supplemental Form

The PHS Fellowship Supplemental Form is used only for fellowship applications.

This form includes fields to upload several attachments including the Specific Aims, Research Strategy, and Applicant Background and Goals.

The attachments in this form should include sufficient information needed for evaluation of the project and fellow, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.





Quick Links

- <u>Introduction</u>
- Fellowship Applicant Section
- Research Training Plan Section
- <u>Sponsor(s), Collaborator(s), and Consultant(s)</u>
 Section
- <u>Institutional Environment and Commitment to</u> <u>Training Section</u>
- Other Research Training Plan Section
- Additional Information Section
- Budget Section
- Appendix

Who should use the PHS Fellowship Supplemental Form:

Use the PHS Fellowship Supplemental Form only if you are submitting a fellowship application.

Fellowship applicants and sponsors are strongly encouraged to speak with a PHS Program Official for Institute- or Center (IC)-specific guidance before preparing this application. Refer to the Table of IC-specific Information, Requirements, and Staff Contacts in your FOA. In addition, a list of contacts specifically for extramural training at the NIH ICs can be found at NIH Training Advisory Committee Research Training Staff Contacts. You are encouraged to check these websites at any time for the most current contact information.

It is important that the attachments in this form be developed in collaboration with your sponsor, but they should be written by you, the fellowship applicant.

Read all the instructions in the FOA before completing this section to ensure that your application meets all IC-specific criteria.

Applicants must follow all policies and requirements related to proprietary information, page limits, and formatting. See the following pages for more information:

- Format Attachments
- Page Limits
- NIH Grants Policy Statement, Section 2.3.11.2: Confidentiality of Information
- NIH Grants Policy Statement, Section 2.3.11.2.2: The Freedom of Information Act

Introduction

1. Introduction (RESUBMISSION)

Who must complete the "Introduction" attachment:

An "Introduction" attachment is required only if the type of application is resubmission or if the FOA specifies that one is needed. An introduction is not allowed for new or renewal applications.

Descriptions of different types of applications are listed here: NIH Types of Applications.

Format:

Follow the page limits for the Introduction in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Resubmission applications: See specific instructions on the content of the Introduction on the NIH's Resubmission Applications page.

Fellowship Applicant Section

2. Applicant's Background and Goals for Fellowship Training

Who must complete the "Applicant's Background and Goals for Fellowship Training" attachment:

The "Applicant's Background and Goals for Fellowship Training" attachment is required.

Format:

Follow the page limits for Applicant's Background and Goals for Fellowship Training in the NIH Table of Page Limits unless otherwise specified in the FOA.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Organize the Applicant's Background and Goals for Fellowship Training attachment in the specified order and use the instructions provided below unless otherwise specified in the FOA. Start each section with the appropriate heading - Doctoral Dissertation and Research Experience, Training Goals and Objectives, Activities Planned Under this Award.

A. Doctoral Dissertation and Research Experience:

Briefly summarize your past research experience, results, and conclusions, and describe how that experience relates to the proposed fellowship. In some cases, a proposed fellowship may build directly on previous research experiences, results, and conclusions. In other situations, past research experiences may lead a candidate to apply for a fellowship in a new or different area of research. Do not list academic courses in this section.

Applicants with no research experience: Describe any other scientific experiences.

Advanced graduate students (i.e., those who have or will have completed their comprehensive examinations by the time of award): Include a narrative of your planned doctoral dissertation (may be preliminary).

Postdoctoral fellowship applicants: Specify which areas of research were part of your predoctoral thesis or dissertation and which, if any, were part of a previous postdoctoral project.

B. Training Goals and Objectives:

- Describe your overall training goals for the duration of the fellowship and how the proposed fellowship will enable the attainment of these goals.
- Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award.
- Discuss how the proposed research will facilitate your transition to the next career stage, if applicable.

C. Activities Planned Under this Award:

The activities planned under this award should be individually tailored and well integrated with your research project.

- Describe, by year, the activities (research, coursework, professional development, clinical activities, etc.) you will be involved in during the proposed award. Estimate the percentage of time to be devoted to each activity. The percentage should total 100 for each year.
- Describe the research skills and techniques that you intend to learn during the award period.
- Describe the planned, non-research activities (e.g. those related to professional development and clinical activities) that you plan to engage in during the award period.
- Provide a timeline detailing the proposed research training and related activities for the entire duration of the fellowship award.

Research Training Plan Section

A Research Training Plan is required for all types of fellowship awards and is a major part of the fellowship application. It is important to relate the proposed research to the applicant's scientific career goals. Explain the relationship between the applicant's research on the fellowship award and the mentor's ongoing research program.

The information in these introductory paragraphs to the Research Training Plan Section applies to all Research Training Plan Section attachments: Specific Aims, Research Strategy, Respective Contributions, Selection of Sponsor and Institution, Progress Report Publication List, and Training in the Responsible Conduct of Research.

For most types of research, the plan should include:

- a specific hypothesis,
- a list of the specific aims and objectives that will be used to examine the hypothesis,
- a description of the methods/approaches/techniques to be used in each aim,
- a discussion of possible problems and how they will be managed, and
- alternative approaches that might be tried if the initial approaches do not work.

The Research Training Plan is expected to be tailored to the experience level of the applicant and to allow him/her to develop the necessary skills for further career advancement. Reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the focus of the Research Training Plan.

Although applicants for fellowship awards are expected to write the Research Training Plan, the mentor should review a draft of the plan and discuss it in detail with the applicant. Review by other knowledgeable colleagues is also helpful. Although it is understood that fellowship applications do not require the extensive experimental detail usually incorporated into regular research grant applications, a fundamentally sound Research Training Plan should be provided.

3. Specific Aims

Who must complete the "Specific Aims" attachment:

The "Specific Aims" attachment is required unless otherwise specified in the FOA.

Format:

Follow the page limits for Specific Aims in the <u>NIH Table of Page Limits</u>, unless otherwise specified in the FOA.

Attach this information as a PDF. See NIH's Format Attachments page.

Content

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 have 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).

4. Research Strategy

Who must complete the "Research Strategy" attachment:

The "Research Strategy" attachment is required.

Format:

Follow the page limits for the Research Strategy in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA. Although multiple sections of information are required in the Research Strategy as detailed below, the page limit applies to the entirety of the single Research Strategy attachment.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Organize the Research Strategy in the specified order and use the instructions provided below, unless otherwise specified in the FOA. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy and provide the full reference in <u>F.220 - R&R Other Project Information Form, Bibliography and References Cited.</u>

1. Significance

- Explain the importance of the problem or critical barrier to progress 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.

2. Innovation

• Fellowship applicants should not include an Innovation section except in the unusual circumstance where it is specified in the FOA.

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the <u>Resource Sharing Plan</u> attachment, 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 the precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment below.

If you have multiple Specific Aims, you may address Significance, Innovation, and Approach either for each Specific Aim individually or 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 (Significance, Innovation, and Approach) listed above.

Preliminary Studies for New Applications:

For new applications, include information on preliminary studies (including data collected by others in the lab), if any. Discuss the applicant's preliminary studies, data, and/or experience pertinent to this application.

Progress Report for Renewal Applications:

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

Renewal applications for individual fellowships are rare. You should consult with your program official before preparing such an application. If 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. In the Progress Report, you should:

- 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.
- Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH Glossary definition for <u>clinical research</u>, particularly if relevant to studies proposed in the renewal application. You should not submit a PHS Inclusion Enrollment Report unless the enrollment is part of new or ongoing studies in the renewal application.

Do not include a list of publications, manuscripts accepted for publication, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment.

5. Respective Contributions

Who must complete the "Respective Contributions" attachment:

The "Respective Contributions" attachment is required.

Format:

Follow the page limits for Respective Contributions in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Describe the collaborative process between you and your sponsor/co-sponsor(s) in the development, review, and editing of this Research Training Plan. Also discuss your respective

roles in accomplishing the proposed research.

6. Selection of Sponsor and Institution

Who must complete the "Selection of Sponsor and Institution" attachment:

The "Selection of Sponsor and Institution" attachment is required.

Format:

Follow the page limits for Selection of Sponsor and Institution in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Describe the rationale/justification for the selection of both the sponsor and the institution.

- 1. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the applicant organization, provide an explanation here.
- 2. Foreign Institution. If you are proposing a research training experience at a foreign institution, describe how 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. The need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.
- 3. Postdoctoral and Senior Fellowship Applicants requesting training at their Doctorate or Current Institution: Training is expected to broaden a fellow's perspective. Therefore, if you are requesting training at either your doctorate institution or any institution where you have been training for more than a year, you 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.

7. Progress Report Publication List (RENEWAL)

Who must complete the "Progress Report Publication List" attachment:

A "Progress Report Publication List" is required only if the type of application is renewal.

Descriptions of different types of applications are listed here: NIH <u>Types of Applications</u>.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

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.



Beginning with application due dates on or after May 25, 2017, you are allowed to cite interim research products. Note: interim research products have specific rules and citation requirements. See related Frequently Asked Questions on citing interim research products and claiming them as products of your NIH award.

Provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for the following types of articles:

- · Articles that fall under the Public Access Policy;
- Articles that were authored or co-authored by the fellowship applicant and arose from NIH support;
- Articles that were authored or co-authored by the fellowship applicant and arose from AHRQ funding provided after February 19, 2016 (see Guide Notice on <u>Policy for Public</u> Access to AHRQ-Funded Scientific Publications).

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." NIH maintains a list of such journals.

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.

8. Training in the Responsible Conduct of Research

Who must complete the "Training in the Responsible Conduct of Research" attachment:

The "Training in the Responsible Conduct of Research" attachment is required.

Format:

Follow the page limits for Training in the Responsible Conduct of Research in the NIH Table of Page Limits unless otherwise specified in the FOA.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the Supplemental Instructions, Part III, Section 1.16: Policy on Instruction in the Responsible Conduct of Research:

- 1. **Format:** Describe 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:** Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics).
- 3. **Faculty Participation:** Describe the role of the mentor(s) and other faculty involvement in the instruction.
- 4. **Duration of Instruction:** Describe the total number of contact hours of instruction, taking into consideration the duration of the program.

5. **Frequency of Instruction:** Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed.

Senior fellows may fulfill the requirement for instruction in RCR by participating as lecturers and discussion leaders.

For more information:

See the NIH Guide Notices on the <u>Availability of Resources for Instruction in the Responsible Conduct of Research</u> and on the <u>Requirement for Instruction in the Responsible Conduct of Research</u>.

See the <u>Supplemental Instructions</u>, <u>Part III</u>, <u>Section 1.16</u>: <u>Policy on Instruction in the Responsible Conduct of Research</u> for information on the NIH Policy on Training in RCR.

Sponsor(s), Collaborator(s), And Consultant(s) Section

9. Sponsor and Co-Sponsor Statements

Who must complete the "Sponsor and Co-Sponsor Statement" attachment:

The "Sponsor and Co-Sponsor Statement" attachment is required. Both the Sponsor and all Co-Sponsors must provide statements as described below.

Format:

Follow the page limits for Sponsor and Co-Sponsor Statements in the <u>NIH Table of Page Limits</u> unless otherwise specified otherwise in the FOA.

The Sponsor and Co-Sponsor Statements must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page.

Content:

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

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

Organize each statement in the specified order and use the instructions below, unless otherwise specified in the FOA. Start each section with the appropriate section heading – Research Support Available; Sponsor's/Co-Sponsor's Previous Fellows/Trainees; Training Plan, Environment, Research Facilities; Number of Fellows/Trainees to be Supervised During the Fellowship; and Applicant's Qualifications and Potential for a Research Career.

Each sponsor and co-sponsor statement must address all of the following sections (A-E).

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, name of the PD/PI, start and end dates, and the amount of the award. If the sponsor's research support will end prior to the end of the proposed training period, the sponsor should describe a contingency plan for how the fellow's research will be supported.

The role of the sponsor/co-sponsor in the Research Training Plan should be described. If one or more co-sponsors is proposed, this plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively.

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

State the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative, and for those five, provide information on their time spent in the lab, their present employing organizations, and their present position titles or occupations.

C. Training Plan, Environment, Research Facilities

The applicant's Research Training Plan should be individualized for the applicant, keeping in mind the candidate's strengths and any gaps in needed skills. The Research Training Plan should be designed to enhance both research and clinical training (if applicable).

Describe the Research Training Plan that you have developed specifically for the fellowship applicant. Be sure to include the following points:

- Include items such as classes, seminars, opportunities for interaction with other groups and scientists, and any professional skills development opportunities.
- 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.

The information contained in the "Training Plan, Environment, Research Facilities" section of the Sponsor's and Co-sponsors' Statements should be coordinated with information provided under the Description of Institutional Environment and Commitment to Training attachment below.

F30 Applications: The Research Training Plan should provide opportunities to integrate clinical experiences during the research training component; a plan for a smooth transition to the clinical training component; and should have the potential to facilitate the applicant's transition to a residency or other program appropriate for his/her career goals. Sponsors and co-sponsors should discuss these clinical aspects of the applicant's training as well.

F31, F32, F33 Applications: The Research Training Plan should facilitate the applicant's transition to the next stage of his/her career. Sponsors and co-sponsors should discuss this aspect of the Research Training Plan as well.

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

Indicate how many pre- and/or post- doctoral fellows/trainees the Sponsor/Co-sponsor is expected to supervise during the award period. Co-sponsor statements must also include this information.

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. Include information about how the Research Training Plan, and your own expertise as the sponsor or co-sponsor, will assist in producing an independent researcher.

10. Letters of Support from Collaborators, Contributors, and Consultants

Note that Letters of Support are not the same as Reference Letters, which are required for some fellowship award applications. For more information about Reference Letters see the NIH Reference Letters page.

Format:

Follow the page limits for Letters of Support from Collaborators, Contributors, and Consultants in the NIH Table of Page Limits unless otherwise specified in the FOA.

Letters of support must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page.

Content:

If any collaborators, consultants, or advisors are expected to make substantive contributions to the fellow's planned project and research training, attach letters of support from those individuals here, describing their anticipated role and contributions.

Institutional Environment And Commitment To Training Section

11. Description of Institutional Environment and Commitment to Training

Who must complete the "Description of Institutional Environment and Commitment to Training" attachment:

The "Description of Institutional Environment and Commitment to Training" attachment is required, and includes "Educational Information" for F30 and F31 applications.

Format:

Follow the page limits for the Description of Institutional Environment and Commitment to Training in the NIH Table of Page Limits unless otherwise specified in the FOA.

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Document a strong, well-established research program related to the candidate's area of interest. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations. Indicate the facilities and other resources that will be made available for both career enhancement and the research proposed in this application. Refer to the resources description in <u>F.220 - R&R Other Project Information Form, Facilities and Other Resources</u>, and information provided in the <u>Sponsor and Co-sponsor Statements</u> attachment.

F30 and F31 applications: Educational Information

Describe the institution's dual-degree (F30) or graduate (F31) program in which the applicant is enrolled. This description should include the structure of the program, the required milestones and their usual timing, the number of courses, any teaching commitments or qualifying exams, and the average time to degree over the past 10 years. Describe the progress/status of the applicant in relation to the program's timeline, and the

frequency and method by which the program formally monitors and evaluates a student's progress.

For F30 applications specifically, describe any clinical tutorials during the graduate research years and any activities to ease transition from the graduate to the clinical years of the dual-degree program. Describe any research-associated activities during the clinical years of the dual-degree program.

Include the name of the individual providing this information at the end of the description. This information is typically provided by the director of the graduate program or the department chair.

Other Research Training Plan Section

Human Subjects

Are Human Subjects Involved? Yes/No

This field is pre-populated from the <u>F.220 - R&R Other Project Information Form</u>.

If you have answered "No": If the answer is "No" to the question "Are Human Subjects Involved?" but your proposed research involves human specimens and/or data from subjects, you must provide a justification in the <u>Protection of Human Subjects</u> attachment below for your claim that no human subjects are involved. You do not need to complete the other questions in the Human Subjects section.

If you have answered "Yes": Consult with your Sponsor and Administrative Officials (AO) at the Sponsoring Institution as you complete this section, and also refer to <u>Supplemental Instructions</u>, <u>Part II</u>.

Note that 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.

Refer to the NIH's Research Involving Human Subjects website for more information.

12. Human Subjects Involvement Indefinite?

An answer to this question is required if you answered "Yes" to the question "Are Human Subjects Involved?" on the F.220 - R&R Other Project Information Form.

Check "Yes" if plans for the involvement of human subjects have not been finalized at the time of application, thus making an IRB review and approval unfeasible at this stage. This situation is also referred to "delayed onset human subjects research." If an award is made, you may not participate in human subjects research until both a Protection of Human Subjects section and the certification of the date of IRB approval has been submitted to and approved by the awarding component.

Check "No" if, at the time of application, the above conditions do not apply to you.

13. Clinical Trial

An answer to this question is required if you answered "Yes" to the question "Are Human Subjects Involved?" on the F.220 - R&R Other Project Information Form.

Check "Yes" or "No" to indicate whether the project includes a clinical trial.

Refer to the NIH Glossary for the definition of a clinical trial.

14. Agency-Defined Phase III Clinical Trial?

An answer to this question is required if you answered "Yes" to the "Clinical Trial?" question above.

Check "Yes" or "No" to indicate whether the project is or includes an NIH-defined Phase III clinical trial.

Refer to the NIH Glossary for the definition of a Phase III clinical trial.

15. Protection of Human Subjects

Who must complete the "Protection of Human Subjects" attachment:

Include a "Protection of Human Subjects" attachment if you answered "Yes" to the question "Are human subjects involved?" on the F.220 - R&R Other Project Information Form.

If you answered "No" to the "Are human subjects involved?" question but your proposed research involves human specimens and/or data from subjects, you must provide a justification in this section for your claim that no human subjects are involved.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use the "Protection of Human Subjects" section to circumvent the page limits of the Research Strategy.

Content:

Refer to <u>Supplemental Instructions</u>, <u>Part II</u> for instructions on this attachment. Additionally, be sure to follow any specific instructions in your FOA.

For more information:

Refer to the NIH's Research Involving Human Subjects website.

16. Data Safety Monitoring Plan

Who must complete the "Data Safety Monitoring Plan" attachment:

Include a "Data Safety Monitoring Plan" attachment if you answered "Yes" to question <u>Clinical Trial</u>? above.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Refer to <u>Supplemental Instructions</u>, <u>Part II</u>, <u>Section 4.1.5</u>: <u>Data and Safety Monitoring Plan</u> for instructions on this attachment.

17. Inclusion of Women and Minorities

Who must complete the "Inclusion of Women and Minorities" attachment:

Include an "Inclusion of Women and Minorities" attachment if you answered "Yes" to the question "Are human subjects involved" on the <u>F.220 - R&R Other Project Information Form</u> and the research does not fall under Exemption 4.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Refer to <u>Supplemental Instructions</u>, <u>Part II</u>, <u>Section 4.2: Inclusion of Women and Minorities</u> for instructions on this attachment.

Additionally, refer to Section F.500 - PHS Inclusion Enrollment Report as well as the Supplemental Instructions, Part II (Section 4.2: Inclusion of Women and Minorities, Section 4.3: Instructions for Completing the PHS Inclusion Enrollment Report, and Section 5.6: NIH Policy on the Inclusion of Women and Minorities in Clinical Research) for more information on submitting PHS Inclusion Enrollment Report as part of your application.

18. Inclusion of Children

Who must complete the "Inclusion of Children" attachment:

Include an "Inclusion of Children" attachment if you answered "Yes" to the question "Are human subjects involved?" on the <u>F.220 - R&R Other Project Information Form</u> and the research does not fall under Exemption 4.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Refer to <u>Supplemental Instructions, Part II</u> (Section 4.4: Inclusion of Children and Section 5.8: NIH Policy on Inclusion of Children).

Vertebrate Animals

Are Vertebrate Animals Used?

This field is pre-populated from the F.220 - R&R Other Project Information Form.

If you have answered "No" for activities involving vertebrate animals and activities involving vertebrate animals are not planned at any time during the proposed project at any performance site: Skip Questions 19 and 20 below.

If you have answered "Yes" for activities involving vertebrate animals: Answer Questions 19 and 20 below in consultation with both your Sponsor and AO.

19. Vertebrate Animals Use Indefinite?

An answer is required if you answered "Yes" to "Are Vertebrate Animals Used?" above.

Check "Yes" if plans for the involvement of vertebrate animals have not been finalized at the time of application, thus making an IACUC review and approval not yet feasible. If an award is made, vertebrate animals may not be used until a "Vertebrate Animals" attachment and certification of IACUC approval has been submitted and approved by the awarding component.

20. Are vertebrate animals euthanized?

An answer is required if you answered "Yes" to "Are Vertebrate Animals Used?" above.

Check "Yes" or "No" to indicate whether animals in the project are euthanized.

If "Yes" to euthanasia, is method consistent with AVMA guidelines?

An answer is required if you answered "Yes" to "Are Vertebrate Animals Euthanized?"

Check "Yes" or "No" to indicate whether the method of euthanasia is consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals.

For more information: See AVMA Guidelines for the Euthanasia of Animals.

If "No" to AVMA guidelines, describe method and provide scientific justification:

If you answered "No" to "Is method consistent with AVMA guidelines?," you must describe (in 1000 characters or fewer) the method of euthanasia and provide a scientific justification for its use.

If you answered "Yes" to "Is method consistent with AVMA guidelines?" skip this question and scientific justification.

21. Vertebrate Animals

Who must complete the "Vertebrate Animals" attachment:

Include a "Vertebrate Animals" attachment if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the <u>F.220 - R&R Other Project Information Form</u>.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use the Vertebrate Animals attachment to circumvent the page limits of the Research Strategy.

Content:

If vertebrate animals are involved in the project, address each of the following criteria:

 Description of Procedures: Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" attachment. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.

- 2. **Justifications:** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- 3. **Minimization of Pain and Distress:** Describe the interventions, including analgesia, anesthesia, sedation, palliative care, and humane endpoints, that will be used to minimize discomfort, distress, pain, and injury.

Provide a concise, complete description of the animals and proposed procedures. In addition to the three points above, you should also:

- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites.
- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

See the following pages for more information:

- NIH's Office of Laboratory Animal Welfare website
- NIH's Vertebrate Animals Section Worksheet
- <u>Supplemental Instructions, Part III, Section 2.2: Vertebrate Animals</u> (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one)

22. Select Agent Research

Who must complete the "Select Agent Research" attachment:

Include a "Select Agent Research" attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

For more information:

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (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. The Centers for Disease Control and Prevention (CDC) and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See the Federal Select Agent Program website.

See also the Supplemental Instructions, Part III, Section 2.13: Select Agent Research.

Content:

Excluded select agents: 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 "Select Agent Research" attachment 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, which is available on the Select Agents and Toxins Exclusions website.

Applying for a select agent to be excluded: 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 HHS 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.

All applicants proposing to use select agents: 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 <u>42 CFR 73.1</u> 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.

23. Resource Sharing Plan

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Data Sharing Plan: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&A) in any budget period 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 (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the FOA 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. **For more information**, see the NIH <u>Data</u> Sharing Policy or the NIH Guide Notice on Sharing Research Data.

Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. For more information, see Supplemental Instructions, Part III, Section 1.5.2: Sharing Model Organism Policy and the NIH Guide Notice on Sharing Model Organisms for Biomedical Research.

Genomic Data Sharing (GDS): Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these

data. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy. **For more information**, see the NIH GDS Policy, the NIH Guide Notice on Genomic Data Sharing Policy, and the GDS website.

Note on GDS: For proposed studies generating human genomic data under the scope of the GDS Policy, an Institutional Certification may be submitted at the time of application submission, but it is not required at that time. The Institutional Certification, however, will be requested as Just-in-Time (JIT) information prior to award. The Institutional Certification, or in some cases, a Provisional Institutional Certification, must be submitted and accepted before the award can be issued.

For more information:

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 Supplemental Instructions, Part III, Section 1.5: Sharing Research Resources.

24. Authentication of Key Biological and/or Chemical Resources

Do not submit an "Authentication of Key Biological and/or Chemical Resources" attachment unless it is specifically requested in the FOA.

Additional Information Section

25. Human Embryonic Stem Cells

Use the following instructions to complete the fields in this section.

For additional guidance, see the NIH Guide Notice on the <u>Change in Requirements for NIH</u> Applications Involving Human Embryonic Stem Cells.

Does the proposed project involve human embryonic stem cells (hESC)?

An answer to this question is required.

If the proposed project involves hESC, check "Yes" and complete the rest of the fields in the Human Embryonic Stem Cells section.

If the proposed project does not involve hESC, check "No" and skip the rest of fields in the Human Embryonic Stem Cells section.

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

If you will use hESC but a specific line from the NIH <u>hESC Registry</u> cannot be chosen at the time of application submission, check this box. Additionally, provide a strong justification (in the Research Strategy) for why an appropriate cell line cannot be chosen from the registry at this time.

If you cannot specify which cell lines will be used at the time of application submission, specific cell line information will be required as Just-in-Time information prior to award.

Cell Line(s):

List the 4-digit registration number of the specific cell line(s) from the NIH hESC Registry (e.g. 0123). Up to 200 lines can be added.

26. Alternate Phone Number

Enter an alternate phone number (e.g., cell phone) for the fellowship applicant. This should be a different number than the one provided in the PD/PI contact information in the <u>F.200 - SF424</u> (R&R) Form.

27. Degree Sought During Proposed Award

Complete the following fields if you will be working toward a degree while receiving fellowship support.

Degree:

Select the type of degree you will be working toward during the proposed award. If the degree is not on the drop down menu, please select "OTH: Other."

If "other," please indicate degree type:

If you selected "OTH: Other" for the "Degree," indicate the type of degree you will be working toward during the proposed award.

Expected Completion Date (month/year):

Enter the expected completion date of the degree sought during the proposed award.

28. Field of Training for Current Proposal

An answer to this field required.

Select a single "Field of Training" code that best describes the proposed area of research training. This information is used for reporting purposes only and is not used for study section assignments.

29. Current or Prior Kirschstein-NRSA Support?

Current or Prior Kirschstein-NRSA Support? Yes/No

An answer to this question is required. Check the appropriate box to indicate whether you currently have or have had prior Kirschstein-NRSA support.

If "Yes," identify current and prior Kirschstein-NRSA support below:

Select the appropriate "Level" and "Type" of Kirschstein-NRSA support. "Level" indicates either predoctoral or postdoctoral level (not the level of experience). "Type" indicates either individual fellowship or institutional research training grant.

If known, enter the start and end dates (month, day, and year) of the support and the grant number (e.g., T32 GM123456 or F31 HL345678) of the current and/or prior support.

You may enter up to four separate listings for current and/or prior support.

Note on Kirschstein-NRSA time limits: An individual cannot receive more than five years of cumulative predoctoral Kirschstein-NRSA support and three years cumulative postdoctoral Kirschstein-NRSA support (the total of institutional grants and individual fellowships) without a waiver from the awarding component. The awarding components have different policies on waiving the statutory limits on support. Therefore, the fellowship applicant must request a waiver from the probable awarding IC before requesting a period of support that would exceed these limits. Refer to the Table of IC-specific Information, Requirements, and Staff Contacts in your FOA. The fellow's sponsor and AOR must endorse the request. The request 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 programs allow for up to six years of predoctoral support).

If you receive additional NRSA support while this application is pending, you must promptly report such information to the awarding component to which this application has been assigned.

30. Applications for Concurrent Support?

Applications for Concurrent Support? Yes/No

An answer to this question is required. Check the appropriate box to indicate whether the fellowship applicant has applied or will be applying for other support that would run concurrently with the period covered by this application.

If yes, please describe in an attached file:

Attach this information as a PDF file. See NIH's Format Attachments page.

If you answered "Yes" to the "Applications for Concurrent Support?" question, you must provide a description of the concurrent support. Include the type, dates, source(s), and amount in the attachment.

If you receive any support from these other applications while this application is pending, you must promptly report such information to the awarding component to which this application has been assigned.

31. Citizenship

Information on Citizenship Requirements for Fellowship Applicants:

Individual NRSA Fellowship Requirements: To be eligible for a Kirschstein-NRSA individual fellowship (F30, F31, F32, F33), the fellowship applicant must be a citizen or non-citizen national of the United States or of its possessions or territories, or must have been lawfully admitted to the United States for permanent residence by the time the award is issued. Individuals on temporary student visas are not eligible for NRSA support unless otherwise specified in the FOA.

Non-NRSA Requirements: If you are 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, F99/K00), you must have a valid visa in your possession that allows you to remain in the United States (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 document in the application that the individual fellowship applicant's visa will allow him or her to remain in the proposed research training setting for the period of time necessary to complete the proposed fellowship. Information may be requested by the NIH or another PHS Agency prior to issuance of an award.

All Fellowship Applicants:

Check the applicable boxes for the following questions:

U.S. Citizen: U.S. Citizen or Non-Citizen National? Yes/No

Check "Yes" if the candidate is a U.S. Citizen or Non-Citizen national; otherwise check "No."

If you answered "Yes," skip the rest of "Question 31. Citizenship" and you can continue with "Question 32. Change of Sponsoring Institution."

If you answered "No," please continue to fill out the rest of "Question 31. Citizenship" following the instructions below.

Non-Citizen nationals are people who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

If "No" to U.S. Citizen or Non-Citizen National, please select the most appropriate response from the options provided:

Non-U.S. Citizen With a Permanent U.S. Resident Visa:

Check this box if the fellowship applicant has been lawfully admitted for permanent residence (i.e., is in the possession of a current and valid Permanent Resident Card or other legal verification of such status).

A notarized statement will be required before an award is issued. The statement must show 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.

Non-U.S. Citizen With a Temporary U.S. Visa:

Check this box if the fellowship applicant currently holds a temporary U.S. visa.

If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, please also check here:

If the fellowship applicant has applied for permanent residence and expects to hold a permanent resident visa by the earliest possible start date of the award, please check this box to indicate that permanent residence status is pending. A notarized statement will be required as a part of the pre-award process.

32. Change of Sponsoring Institution

Check this box if you are submitting your application with a change of sponsoring institution. If the box is checked, you must also provide the name of the former sponsoring institution.

Budget Section

1. Tuition and Fees

Who must complete the "Tuition and Fees" section:

All fellowship applicants must complete this "Tuition and Fees" section.

Content:

Indicate whether funds are being requested for tuition and fees by checking the appropriate box ("None Requested" or "Funds Requested").

Predoctoral Fellowship Applicants: List, by year, the estimated costs of tuition and fees.

Postdoctoral and Senior Fellowship Applicants: List, by year, the costs associated with specific courses that both support the research training experience and that are identified and described in the "Activities Planned Under this Award" section of the <u>Applicant's Background and Goals for Fellowship Training attachment.</u>

For more information:

In accordance with NIH Guide Notice on <u>Ruth L. Kirschstein National Research Service Award Policy</u>, funds to offset the costs of health insurance are included in the standard Institutional Allowance, and are not to be requested as part of Tuition and Fees.

Refer to the NIH <u>Research Training and Career Development</u> website for helpful resources and FAQs about tuition and fees.

2. Present Institutional Base Salary

Who must complete the "Institutional Base Salary" section:

Only senior fellowship applicants should complete the "Institutional Base Salary" section.

Amount:

Provide your present base salary. The value must be in U.S. dollars.

Academic Period:

Indicate the period of time on which the salary is determined (e.g., academic year of 9 months, full-time 12 months, etc.).

Number of Months:

Indicate the number of months per year you receive your base salary. The number may not be more than 12, but may include a decimal to indicate partial months (e.g., 9.5).

3. Stipends/Salary During First Year of Proposed Fellowship

Who must complete the "Stipends/Salary During First Year of Proposed Fellowship" section:

Only senior fellowship applicants should complete the "Stipends/Salary During First Year of Proposed Fellowship" section.

a. Federal Stipend Requested: Amount and Number of Months

Enter the amount of the stipend being requested for the initial period of support (i.e., the first year of proposed fellowship) and the number of months requested.

b. Supplementation from other sources: Amount, Number of Months, Type, and Source

Enter the anticipated amount and the number of months (during the first year of the proposed fellowship) for any stipend/salary supplementation. Also enter the type of supplementation expected (e.g., sabbatical leave, salary, etc.) and the source of such funding.

Appendix

Appendix



Refer to the FOA to determine whether an appendix is allowed in your application.

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. 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.

For materials that cannot be submitted electronically or materials that cannot be converted to PDF (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Do not use the Appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. For additional information regarding appendix material and page limits, refer to the NIH Guide Notice on Compliance with NIH Application Format and Content Instructions.

Use file names for attachments that are descriptive of the content.

A summary sheet listing all of the items included in the Appendix is encouraged but not required. When including a summary sheet, it should be included in the first Appendix attachment.

Content:

The only allowable appendix materials are:

For applications proposing clinical trials (unless the FOA provides other instructions for these materials):

- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND), as appropriate

For all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items
 - o If Appendix materials are required in the FOA, review criteria for that FOA will

address those materials, and applications submitted without those Appendix materials will be considered incomplete and will not be reviewed.

Note: Applications that do not follow the appendix requirements will not be reviewed. Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this section.

For more information:

- Information that expands upon or complements information provided in any section of the application even if it is not required for the review is not allowed in the Appendix unless it is listed in the allowed appendix materials above. For more information, see the NIH Guide Notice on Compliance with NIH Application Format and Content Instructions.
- Unless the FOA requires that certain information be included in the Appendix, failure of
 reviewers to address appendix materials in their reviews is not an acceptable basis for an
 appeal of initial peer review. For more information, see the NIH Guide Notice on <u>Appeals of
 NIH Initial Peer Review</u>.
- Appendix Policy Frequently Asked Questions

F.500 - PHS Inclusion Enrollment Report

The PHS Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

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

See below for form-specific instructions and refer to Supplemental Instructions, Part II Section 4.3: Instructions for Completing the PHS Inclusion

<u>Enrollment Report(s)</u> for additional guidance on how and when to use the PHS Inclusion Enrollment Report.





Who should use the PHS Inclusion Enrollment Report?

The PHS Inclusion Enrollment Report is required for any application that involves NIH-defined clinical research. Refer to the NIH Glossary for the definition of a <u>clinical research</u>.

For more information on how to use the PHS Inclusion Enrollment Report:

Refer to the <u>Supplemental Instructions</u>, <u>Part II</u>, <u>Section 4.3: Instructions for Completing the PHS Inclusion Enrollment Report(s)</u> for additional guidance on how and when to use the PHS Inclusion Enrollment Report. The section has general guidance as well as specific guidance for different application types, applications involving more than one study, and applications with multi-site studies.

Study Title (must be unique):

This field is required.

The Study Title can have a maximum of 250 characters.

Enter a unique title that describes the study the participants will be involved in. If there is more than one study, provide a separate Study Title for each.

Delayed Onset Study (Yes/No)?

This field is required.

Check the appropriate box to indicate whether the study is considered delayed onset. If the study is delayed onset, select "Yes." If the study is not delayed onset, select "No."

"Delayed onset" generally means that a study has not been developed and cannot be described in terms of human subjects' protections and inclusion. This does NOT apply to a study that can be described but will not start immediately.

For additional guidance on whether a study meets the criteria to be considered "delayed onset,", refer to the <u>Supplemental Instructions</u>, <u>Part II</u>, <u>Section 2</u>. <u>Scenario D: Delayed-Onset Human</u> <u>Subjects Research</u>.

If you have answered "Yes" to the "Delayed Onset Study?" question, the rest of that particular PHS Inclusion Enrollment Report will be disabled. Complete additional PHS Inclusion Enrollment Reports, if applicable.

If you have answered "**No**" to the "Delayed Onset Study?" question, you must answer the following questions and complete the enrollment table:

Enrollment Type (Planned/Cumulative):

This field is required.

Select whether the enrollment table reflects:

Planned Enrollment: Individuals will be recruited into the study (and/or individuals have already been recruited and continue to be part of the study).

Cumulative (Actual) Enrollment: Studies use an existing dataset or resource.

Using an Existing Dataset or Resource (Yes/No):

This field is required.

Select whether this study involves use of an existing dataset or resource.

"Using an existing dataset or resource" generally means that investigators are utilizing data from a previous study or data bank. Do NOT answer "Yes" for individuals previously recruited specifically for this study.

For additional guidance on what is considered an existing dataset, refer to <u>Supplemental Instructions</u>, Part II, Section 4.2: Inclusion of Women and Minorities and these NIH <u>Frequently Asked Questions on Monitoring Inclusion when Working with Existing Datasets and/or Resources</u>.

Enrollment Location (Domestic/Foreign):

This field is required.

Select whether the participants described in the Inclusion Enrollment Report are based at a U.S. or at a non-U.S. site. At a minimum, participants at U.S. and non-U.S. sites must be reported separately (i.e., on separate PHS Inclusion Enrollment Reports), even if it is for the same study.

For additional guidance on how to complete the PHS Inclusion Enrollment Report if you will be working with non-U.S. populations, refer to these Frequently Asked Questions on Monitoring Inclusion in Non-US Research Participants.

Clinical Trial (Yes/No):

This field is required.

Select whether the study these participants are involved in is considered a clinical trial.

Refer to the NIH Glossary for the definition of a clinical trial.

NIH-Defined Phase III Clinical Trial (Yes/No):

This field is required.

Select whether the study is an NIH-defined Phase III clinical trial.

Refer to the NIH Glossary for the definition of a Phase III clinical trial.

Comments:

Your comments can have a maximum of 500 characters.

Enter information you wish to provide about this PHS Inclusion 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.

Racial Categories:

American Indian/Alaska Native:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

Asian:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both Asian **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Asian **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

Native Hawaiian or Other Pacific Islander:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both Native Hawaiian or Other Pacific Islander **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Native Hawaiian or Other Pacific Islander **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

Black or African American:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both Black or African American **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Black or African American **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

White:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both White **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both White **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

More than One Race:

These fields are required.

Enter the expected number of females and males (in the respective fields) who both identify with more than one racial category **and** are Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who both identify with more than one racial category **and** are Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

Unknown or Not Reported:

These fields are required.

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. 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. Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are both of unknown/not reported race and of unknown/not reported ethnicity. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative").

Total:

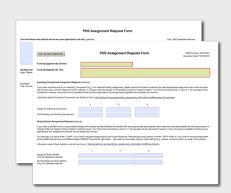
The total fields at the bottom will be automatically calculated and reflect the totals of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino and of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino. Use the "Unknown/Not Reported" fields only when reporting actual enrollment (i.e., your "Enrollment Type" is "Cumulative"). The "Total" fields in the right column will be automatically calculated to total all individuals in a given racial category.

F.600 - PHS Assignment Request Form

The PHS Assignment Request Form may be used to communicate specific application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs).

This information will not be part of your assembled application, and it will neither be made available to program staff nor provided to reviewers. It is used specifically to convey additional, optional information about your preference(s) for assignment and review of your application to DRR and SROs.

This information was previously collected in the Cover Letter Attachment, but must now be provided in the PHS Assignment Request Form.





Completing the PHS Assignment Request Form:

This form is optional. Use it only if you wish to make specific assignment or review requests. There is no requirement that all fields or all sections be completed. You have the flexibility to enter a single request or to provide extensive information using this form.

Note on Application Assignments: The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to NIH Institutes/Centers (ICs) and other PHS agencies for funding consideration. DRR also assigns applications to NIH Scientific Review Groups (SRGs) and Special Emphasis Panels (SEPs).

Awarding Component Assignment Request (optional)

To facilitate accurate communication of your request to NIH referral and review staff, use the short abbreviation (e.g., NCI for the National Cancer Institute).

While NIH staff will consider all assignment requests, in some cases the reviewing IC is predetermined and assignment requests cannot be honored.

Descriptions of the scientific areas covered by all NIH ICs and links to other PHS agency information can be found on the PHS Assignment Information website.

You do not need to make entries in all six boxes of the "Awarding Component Assignment Request" section.

Assign to Awarding Component:

Enter up to three preferences for primary assignment in the boxes in the "Assign to Awarding Component" row. Use the column labeled "1" to enter your first choice.

Do Not Assign to Awarding Component:

Enter up to three preferences to which you do not want your application assigned. Enter your preferences in the boxes in the "Do Not Assign To Awarding Component" row. Use the column labeled "1" to enter your first choice.

Study Section Assignment Request (optional)

To facilitate accurate communication of your request to NIH referral and review staff, use the short abbreviation of the SRG/SEP you wish to request. For example, enter "CAMP" for the Cancer Molecular Pathobiology study section or enter "ZRG1 HDM-R" for the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

More information about how to identify CSR and NIH SRGs and SEPs, including their short abbreviations, can be found on CSR Study Sections and Special Emphasis Panel.

While the majority of NIH research grant and fellowship applications are reviewed by CSR, some are assigned to individual IC review groups and some are clustered for review in SRGs/SEPs without flexibility for honoring review requests. However, it is standard practice to honor such requests whenever possible, depending on existing locus of review agreements within NIH and other PHS agencies.

You do not need to make an entry in all six boxes of the "Study Section Assignment Request" section.

Assign to Study Section:

Enter up to three preferences for SRGs/SEPs in the boxes in the "Assign to Study Section" row. Use one box per individual SRG/SEP request. Use the column labeled "1" to enter your first choice.

Do Not Assign to Study Section:

Enter up to three preferences for SRGs/SEPs to which you do not want your application assigned. Enter your preferences in the boxes in the "Do Not Assign To Study Section" row. Use the column labeled "1" to enter your first choice.

List Individuals who should not review your application and why (optional)

List specific individuals who should not review your application and why they should not review your application. Provide sufficient information (e.g., name, organizational affiliation) so that the SRO can both correctly identify the individual and be prepared to confirm a conflict of interest if the SRO contacts you for an explanation. Simply stating "Dr. John Smith is in conflict with my application" is not helpful.

Your answer can have a maximum of 1000 characters.

Identify Scientific areas of expertise needed to review your application (optional)

List up to five general or specific types of expertise needed for the review of your application. Limit your answers to areas of expertise – do not enter names of individuals you would like to review your application.

Each field can have a maximum of 40 characters.

Form Screenshots

Quick Links

- SF 424 (R&R) Form
- R&R Other Project Information Form
- Project/Performance Site Location(s) Form
- R&R Senior/Key Persons Profile (Expanded)
- PHS Fellowship Supplemental Form
- PHS Inclusion Enrollment Report
- PHS Assignment Request Form

F - i

SF 424 (R&R) Form

APPLICATION FOR FEDI	ERAL ASSISTANCE	3. DATE RECEIVED BY STATE State Application Identifier
SF 424 (R&R)		
1. TYPE OF SUBMISSION		4. a. Federal Identifier
Pre-application Appli	cation Changed/Correct	ed Application b. Agency Routing Identifier
2. DATE SUBMITTED	Applicant Identifier	
		c. Previous Grants.gov Tracking ID
5. APPLICANT INFORMATIO	N .	Organizational DUNS:
.egal Name:		
Department		Division:
Street1:		
Street2:		
City:		County / Parish:
State:		Province:
Country:	USA: UNITED STAT	TES ZIP / Postal Code:
	tters involving this application	
Prefix:	First Name:	Middle Name:
Last Name:		Suffix:
Position/Title:		
Street1:		
Street2:		County Codeby
City:		County / Parish: Province:
Country:		ZID I Double Code
Phone Number:	USA: UNITED STA	Number:
Email:	1 80.	Thursday.
S. EMPLOYER IDENTIFICAT	ON (EIN) or (TIN):	
7. TYPE OF APPLICANT:		Please select one of the following
Other (Specify):		rease select one of the following
Small Business Organizati	on Type Women Own	ed Socially and Economically Disadvantaged
TYPE OF APPLICATION:	If R	Sevision, mark appropriate box(es).
New Resultantission	m [A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration
Renewal Continual	ion Revision	E. Other (specify):
s this application being submi	tted to other agencies? Yes	No What other Agencies?
9. NAME OF FEDERAL AGE	NCY:	10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
		TITLE:
14 DESCRIPTIVE TITLE OF	ADDI ICANTIS DOCIECT	
11. DESCRIPTIVE TITLE OF	AFFERDANT'S PROJECT:	
12. PROPOSED PROJECT: Start Date Ending Da		NAL DISTRICT OF APPLICANT

Form Screenshots F - ii

SF 424 (R&R) APPLICATION FOR FEDERAL AS	SISTANCE Page 2
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT I	
Prefix: First Name:	Middle Name:
Last Name:	Suffix:
Position/Title:	
Organization Name:	
Department: Division:	
Street1:	
Street2: City: County /	Porish:
State:	Province:
Country	ZIP / Postal Code:
Phone Number: USA: UNITED STATES Phone Number: Fax Number:	ZII 71 Ostal Octob
Email:	
	AS AS ADDITIONAL OF THE PERSON OF THE PARTY
15. ESTIMATED PROJECT FUNDING	16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
a. Total Federal Funds Requested	a. 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	b. NO PROGRAM IS NOT COVERED BY E.O. 12372; OR
	PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW
	provide the required assurances * and agree to comply with any resulting fraudulent statements or claims may subject me to criminal, civil, or this list, is contained in the announcement or agency specific instructions.
18. SFLLL (Disclosure of Lobbying Activities) or other Explanator	y Documentation
	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 / Pai	rish:
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
Completed on Submitterion to Stallts.you	
20. Pre-application	Add Attachment Delete Attachment View Attachment
21. Cover Letter Attachment	Add Attachment Delete Attachment View Attachment

F - iii

Other Project Information Form

RESEARCH & RELATED Other Project Information	OMB Number: 4040-0001 Expiration Date: 6/30/2016
Are Human Subjects Involved? 1.a. If YES to Human Subjects No	
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:	
3. Is proprietary/privileged information included in the application?	
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 a environmental impact statement (EIS) been performed? Yes No	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:	
6.b. Optional Explanation:	
7. Project Summary/Abstract Add Attachment Delete Attachment	View Attachment
8. Project Narrative Add Attachment Delete Attachment View	Attachment
9. Bibliography & References Cited Add Attachment Delete Attachment	ment View Attachment
10. Facilities & Other Resources Add Attachment Delete Attachmen	nt View Attachment
11. Equipment Delete Attachment View Attachm	nent
12. Other Attachments Add Attachments Delete Attachments View Attachments	

F - iv Form Screenshots

Project/Performance Site Location(s) Form

OMB Number: 4040-0010

	Pi	roject/Pertormanc	e Site Location(s)	}
Project/Performance	Site Primary Location		application as an individua nment, academia, or other	al, and not on behalf of a company, state, r type of organization.
Organization Name:				
DUNS Number:				
* Street1:				
Street2:				
* City:			County:	
* State:				
Province:				
* Country: USA: U	NITED STATES			
* ZIP / Postal Code:			* Project/ Performance	e Site Congressional District:
Project/Performance Organization Name: DUNS Number: * Street1: Street2: * City:	e Site Location 1		application as an individua nment, academia, or other	al, and not on behalf of a company, state, * type of organization.
* State:			County.	
Province:				
* Country: USA: U	MITTED CHATEC			
* ZIP / Postal Code:	MILLO STATES		* Project/ Performance	e Site Congressional District:
Additional Location	(s)		Add Attachment D	velete Attachment View Attachment

Form Screenshots F - v

Senior/Key Persons Profile (Expanded)

OMB Number: 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

	PROFILE - Project Director/Principal Investigator
Prefix:	* First Name: Middle Name:
* Last Name:	Suffix:
Position/Title:	Department:
Organization Nar	ne: Division:
* Street1:	
Street2:	
* City:	County/ Parish:
* State:	Province:
* Country:	* Zip / Postal Code:
* Phone Number:	Fax Number:
* E-Mail:	
Credential, e.g.	, agency login:
* Project Role:	PD/PI Other Project Role Category:
Degree Type:	
Degree Year:	
*Attach Biog	graphical Sketch Add Attachment Delete Attachment View Attachment
Attach Curre	ent & Pending Support Add Attachment Delete Attachment View Attachment
	PROFILE Saniavikas Paman 4
Prefix:	PROFILE - Senior/Key Person 1 * First Name: Middle Name:
* Last Name:	riist Name.
Position/Title:	Department:
Organization Nar	
* Street1:	
Street2:	
* City:	County/ Parish:
* State:	Province:
* Country: USA:	UNITED STATES *Zip/Postal Code:
* Phone Number:	
* E-Mail:	
Credential, e.g.,	, agency login:
* Project Role:	Other Project Role Category:
Degree Type:	
Degree Year:	
Attach Biog	raphical Sketch Add Attachment Delete Attachment View Attachment
Attach Curre	ent & Pending Support Add Attachment Delete Attachment View Attachment
	Nort Doman

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.

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PHS Fellowship Supplemental Form

PHS Fellowship Supplemental Form

	OMB Number: 0925-000
Introduction 1. Inroduction (for Resubmission)	Add Attachment Delete Attachment View Attachment
(ioi resdumission)	
Fellowship Applicant Section	
Applicant's Backround and Goals for Fellowship Training	Add Attachment Delete Attachment View Attachment
Research Training Plan Section	
3. Specific Aims	Add Attachment Delete Attachment View Attachment
4. Research Strategy	Add Attachment Delete Attachment View Attachment
5. Respective Contributions	Add Attachment Delete Attachment View Attachment
Selection of Sponsor and Institution	Add Attachment Delete Attachment View Attachment
7. Progress Report Publication List (for RENEWAL applications only)	Add Attachment Delete Attachment View Attachment
Training in the Responsible Conduct of Research	Add Attachment Delete Attachment View Attachment
Sponsor(s), Collaborator(s), and Consultant(s) Section	
9. Sponsor and Co-Sponsor Statements	Add Attachment Delete Attachment View Attachment
10. Letters of Support from Collaborators, Contributors, and Consultants	Add Attachment Delete Attachment View Attachment
Institutional Environment and Commitment to Training Section	on
Description of Institutational Envirornment and Commitment to Training	Add Attachment Delete Attachment View Attachment

Form Screenshots F - vii

TI 611 1 1 1 1 1 1			OIL D :				-	
The following item is taken for this item must be made of						epeated here for y	our refere	nce. Any change
Are H	uman Subjec	ts Involved?	☐ Yes	s 🗌 No				
12. Human Subjects Involvement Indefinite?	☐ Yes	□ No						
13. Clinical Trial?	☐ Yes	☐ No						
14. Agency-Defined Phase III Clinical Frial?	☐ Yes	□ No						
15. Protection of Human Subjects				Add Attachm	ent	Delete Attachme	ent \	/iew Attachment
16. Data Safety Monitoring Plan				Add Attachm	ent	Delete Attachme	ent \	/iew Attachment
17. Inclusion of Women and Minorities				Add Attachm	ent	Delete Attachm	ent	View Attachment
18. Inclusion of Children				Add Attachm	ent	Delete Attachme	ent \	/iew Attachment
The following item is taken to this item must be made	from the Rese on the Resea	earch & Relate	d Other Pro	ject Information f	orm and	repeated here for	your refer	ence. Any change
The following item is taken to this item must be made	on the Resea	earch & Relate rch & Related Animals Usec	Other Proje	ct Information for	form and m.	repeated here for	your refer	ence. Any change
The following item is taken to this item must be made	on the Resea	rch & Related	Other Proje	ct Information for	orm and m.	repeated here for	your refer	ence. Any change
The following item is taken to this item must be made ### Application of the content of the con	on the Resea	rch & Related Animals Used	Other Proje	ct Information for	orm and m.	repeated here for	your refer	ence. Any change
The following item is taken to this item must be made 4 19. Vertebrate Animals Use Indefinite?	on the Resear	Animals Used	Other Proje	ct Information for	orm and	repeated here for	your refer	ence. Any change
The following item is taken to this item must be made 4. 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with An	on the Resear	Animals Used No No No No nary Medical	Other Project	ct Information for	orm and m.	repeated here for	your refer	ence. Any change
The following item is taken to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with An Association (AVMA) guidelining if "No" to AVMA guidelines, desprovide a scientific justification	on the Resear	Animals Used No No No No nary Medical	Other Proje	ct Information for	m.	repeated here for		ence. Any change
The following item is taken to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with An Association (AVMA) guideline. If "No" to AVMA guidelines, des provide a scientific justification	re Vertebrate Yes Yes errican Veterines?	Animals Used No No No No nary Medical	Other Proje	ies No	m.			
The following item is taken to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with An Association (AVMA) guideline if "No" to AVMA guidelines, des provide a scientific justification 21. Vertebrate Animals Other Research Training Plan Information	re Vertebrate Yes Yes errican Veterines?	Animals Used No No No No nary Medical	Other Project	ies No	De		Viev	
to this item must be made 49. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with An Association (AVMA) guidelin- If "No" to AVMA guidelines, des	re Vertebrate Yes Yes errican Veterines?	Animals Used No No No No nary Medical	Other Proje	es No	De	lete Attachment	Viev	v Attachment

Form Screenshots F - viii

Additional Information Section
25. Human Embryonic Stem Cells
* 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 llist: 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) (Example:0004): Add
26. Alternate Phone Number
27. Degree Sought During Proposed Award:
Degree If "other", please indicate degree type If "other", please indicate degree type Expected Completion Date (MM/YYYY):
28.*Field of Training for Current Proposal 29. *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
Add 30. *Applications for Concurrent Support?
31. * Citizenship U.S. Citizen U.S. Citizen or Non-Citizen National Non-U.S. Citizen With a Permanent U.S. Resident Visa With a Temporary U.S. Visa If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expects to hold a permanent resident visa by the earliest possible start date of the award, please also check here.
Name of Former Institution 32.

Form Screenshots F - ix

All Fellowship Applicants:						
1. * Tuition and Fees: None Re	quested 🗌 Fun	ds Requeste	ed			
Yea	r 1					
Yea	r 2					
Yea	r 3					
Yea	r 4					
Yea	r 5					
Yea	r 6 (if applicable)					
Tota	al Funds Requested:					
100	ar r unuo rroquottour					
Senior Fellowship Applicants Only	Amount		Academic Period	Nur	ber of Months	
2. Present Institutional Base Salary:				14411	DCT OF WORKING	Reset Ent
Stipends/Salary During First Year of Proposed Fellowship						
	Amount		Number of Months			
a. Federal Stipend Requested:						
b. Supplementation from other sources:	Amount		Number of Months			
	Type (sabbatical leave	e, salary, etc	.)			
	Source					1

Form Screenshots F - x

PHS Inclusion Enrollment Report

View Burden Statement PHS Inclusion Enrollment Report This report format should NOT be used for collecting data from study participants. OMB Number: 0925-0001 and 0925-0002 Expiration Date: 10/31/2018											
*Study Title (must be unique):	(must be										
* Delayed Onset Study? Yes No											
If study is not delayed onset, the following selections are required:											
		Enrollment Ty	/pe		Planned	Cumulative (A	ctual)				
		Using an Exis	ting Dataset or	Resource	Yes	No					
		Enrollment Lo	ocation		Domestic	Foreign					
		Clinical Trial			Yes	No	NII	H-Defined Phase	e III Clinical Tria	al Yes	No No
Comments:											
		Not	Hispanic or La	tino	Ш	Ethnic C	ategories	Linknown	/Not Paparted	Ethnicity	Total
Racial Cate	egories	INOL	mispariic or La	Unknown/	П	spariic or Laur	Unknown/	Unknown/Not Reported Ethnicity Unknown/			Total
		Female	Male	Not Reported	Female	Male	Not Reported	Female	Male	Not Reported	
American Ind Alaska Native		0	0	0	0	0	0	0	0	0	0
Asian		0	0	0	0	0	0	0	0	0	0
Native Hawa Other Pacific		0	0	0	0	0	0	0	0	0	0
Black or Afric American	can	0	0	0	0	0	0	0	0	0	0
White		0	0	0	0	0	0	0	0	0	0
More than Or	ne Race	0	0	0	0	0	0	0	0	0	0
Unknown or I Reported	Not	0	0	0	0	0	0	0	0	0	0
Total		0	0	0	0	0	0	0	0	0	0
					Rep	ort 1 of 1					
< Previous	s Report				De	lete Report					Next Report >

To ensure proper performance, please save frequently.

Form Screenshots F - xi

PHS Assignment Request Form

View Burden Statement	PHS	OMB Number: 0925-0001 Expiration Date: 10/31/2018		
Funding Opportunity Number:				
Funding Opportunity Title:				
Awarding Component Assignment Reques	st (optional)			
	stitute) in "Assign to/Do Not	Assign To Awarding Compone	ent" sections below. Your first o	nost appropriate assignment then enter the short choice should be in column 1. All requests will be
Information about Awarding Components can	be found here: https://grants	s.nih.gov/grants/phs_assignme	ent_information.htm#Awarding	Components
	1	2	3	
Assign to Awarding Component:				
Do Not Assign to Awarding Component:				
Study Section Assignment Request (option	nal)			
	ctions below. Your first choic			nter the short abbreviation for that study section in wever, locus of review is predetermined for some
				ZRG1 HDM-R" if you wish to request assignment paces, hyphens) when you type in the request.
Information about Study Sections can be four	nd here: https://grants.nih.go	v/grants/phs_assignment_info	rmation.htm#Study Section	
	1	2	3	
Assign to Study Section: Only 20 characters allowed				
Do Not Assign to Study Section: Only 20 characters allowed				

PHS Assignment Request Form

List Individuals who should not	ist Individuals who should not review your application and why (optional)									
	lentify Scientific areas of expertise needed to review your application (optional) ote: Please do not provide names of individuals									
	1	2	3	4	5					
Expertise: Only 40 characters allowed										

Form Screenshots F - xii