FORMS VERSION E SERIES

UPDATED SEPTEMBER 25, 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)

TABLE OF CONTENTS

TABLE OF CONTENTS 2

F.100 - How to Use the Application Instructions 3

F.110 - Application Process 5

F.120 - Significant Changes 9

F.130 - Program Overview 11

F.200 - SF 424 (R&R) Form 13

F.220 - R&R Other Project Information Form 28

F.230 - Project/Performance Site Location(s) Form 38

F.240 - R&R Senior/Key Person Profile (Expanded) Form 43

F.430 - PHS Fellowship Supplemental Form 54

F.500 - PHS Human Subjects and Clinical Trials Information 76

F.600 - PHS Assignment Request Form 108

Form Screenshots i

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 funding opportunity announcement, 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
- 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 F.110 - Application Process 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 Selecting the Correct Application Instructions 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 F.130 - Program Overview section for context for program specific instructions.

Step 5. Stay informed of policy changes and updates.

- Refer to the F.120 - Significant Changes 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 and Register
- 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 Grants.gov, eRA Commons, 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 web-based 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 changed/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 - September 25, 2017

SF424 Research and Related (R&R) Form Changes

FORMS-E application packages incorporate the latest versions of the federal-wide forms managed by Grants.gov (OMB Number: 4040-0001, Expiration Date: 10/31/2019).

R&R Other Project Information Form

- Added exemption numbers 7 and 8 to question 1.a; however, these exemptions will not be used at this time.

Forms-E Changes

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

- Updated biosketch instructions so that scholastic performance requires only scientific/professional graduate courses to be listed

PHS Assignment Request Form

- Updated OMB Expiration Date to 03/31/2020
- Clarifications made to instructions

PHS Fellowship Supplemental Form

- Updated OMB Expiration Date to 03/31/2020
- Removed Human Subjects sub-section from Other Research Training Plan Section, including:

  - "Human Subjects Involvement Indefinite" question
  - "Clinical Trial" question
  - "Agency Defined Phase III Clinical Trial" question
  - Protection of Human Subjects attachment
  - Data Safety Monitoring Plan attachment
  - Inclusion of Women and Minorities attachment
  - Inclusion of Children attachment

- Clarified that the Research Strategy attachment should be used to discuss the overall strategy, methodology, and analyses of the proposed research, but applicants should not duplicate information collected in the new PHS Human Subjects and Clinical Trials Information form
- Included instruction to describe research methods for trials that randomize groups or deliver interventions to groups
- Removed "Vertebrate Animals Use Indefinite" question from the Vertebrate Animals sub-section of the Other Research Training Plan Section
- Renumbered form fields
- Made minor text edits
- Includes the updated appendix policy that goes into effect for applications due on or after January 25, 2018. This policy eliminates clinical trial-related materials. See the NIH Guide Notice on Allowable Appendix Materials for more information.

PHS Human Subjects and Clinical Trials Information

- Introduced new form for consolidated human subjects, inclusion enrollment report, and clinical trial information
- Includes attachment to comply with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. See the NIH Guide Notice on Notice of Extension of Effective Date for more information.
- Added exemption numbers 7 and 8 to question 1.3; however, these exemptions will not be used at this time

PHS Inclusion Enrollment Report

- Discontinued use (data collection moved to new PHS Human Subjects and Clinical Trials Information form)

Supplemental Instructions

- Discontinued use of Supplemental Instructions for all competing applications and progress reports
- All information has been folded into the Application Form Instructions and/or is contained in the appropriate policy website (e.g., NIH Grants Policy Statement)

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 11.4: Payback Requirements.

Before Applying:

1. **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 F Kiosk and the AHRQ-Sponsored Training Opportunities 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.

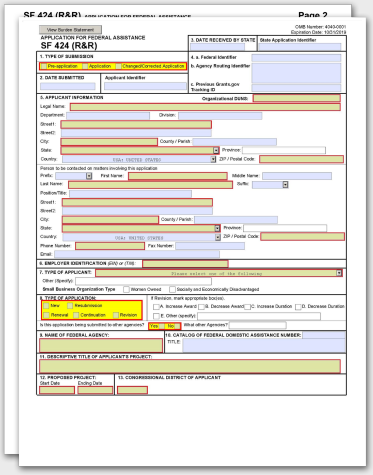
The following chart provides a list of fellowship activity codes. Since this information is subject to change, prospective applicants are encouraged to review the F Kiosk for the most current program information.

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.



View larger image

Quick Links

1. Type of Submission
2. Date Submitted and Applicant Identifier
3. Date Received by State and State Application Identifier

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
10. Catalog of Federal Domestic Assistance Number and Title
11. Descriptive Title of Applicant's Project
12. Proposed Project
13. Congressional District of Applicant
14. Project Director/Principal Investigator Contact Information
15. Estimated Project Funding
16. Is Application Subject to Review by State Executive Order 12372 Process?
17. Certification
18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation
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 Types of Applications 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 Dun & Bradstreet 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 44-4444444. 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 Types of Applications.

- **New.** Check this option when submitting an application for the first time or in accordance with other submission policies. See the NIH Grants Policy Statement, Section 2.3.7.4: Submission of Resubmission Application.
- **Resubmission.** Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH Application Submission Policies. 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

Revisions. For more information on administrative supplements, see NIH Administrative 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.

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 F.240 - R&R Senior/Key Person Profile (Expanded) Form 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 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 NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates.

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, Disclosure of Lobbying Activities) or other documents in this item.

For more information:

See the NIH Grants Policy Statement, Section 4.1.17: Lobbying Prohibition, 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 Application Submission 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.

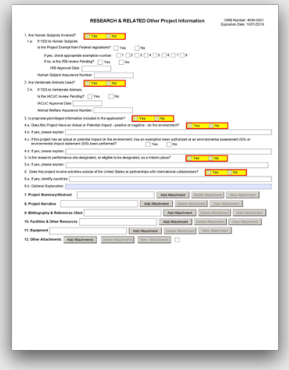
7. When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, the video will not be accepted. See NIH Grants Policy Statement, Section 2.3.7.7: Post Submission Grant Application Materials for additional information.
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 Grants Policy Statement, Section 2.3.7.10: NIH Genomic Data Sharing and Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/Policy for Genome-Wide Association Studies (GWAS)).

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.



View larger image

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. Is proprietary/privileged information included in the application?

4. Environmental Questions

5. Is the research performance site designated, or eligible to be designated, as a historic place?

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

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 "Are Human Subjects Involved" section.

Whether you answer "Yes" or "No" to the "Are Human Subjects Involved?" question here, your answer will populate the relevant field in the F.500 – PHS Human Subjects and Clinical Trials Information form. Follow the F.500 – PHS Human Subjects and Clinical Trials Information form instructions to complete the relevant questions in that form.

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. If you check "No" to "Are Human Subjects Involved?" but your application proposes using human specimens or data, you will be required to provide a clear justification about why this use does not constitute human subjects research. Follow the F.500 – PHS Human Subjects and Clinical Trials Information form instructions.

For more information on human biospecimens or data: Refer to the NIH page on Frequently Asked Questions on Human Specimens, Cell Lines, or Data and the Research Involving Private Information or Biological Specimens flowchart.

Additional Instructions for Fellowship:

In many instances, the fellow will be participating in research supported by a research project grant 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.

1.a. If YES to Human Subjects

Your answers here in question "1.a. If YES to Human Subjects" will populate the corresponding fields in the F.500 – PHS Human Subjects and Clinical Trials Information form.

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, 7, 8:

If you selected "Yes" to "Is the Project Exempt from Federal Regulations," select the appropriate exemption number. **Do not select exemption 7 or 8, as these are not yet being used.**

The 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 the NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures 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 F.200 - SF424 (R&R) Form, is declaring that it will comply with 45 CFR 46 and proceed to obtain a FWA (see Office for Human Research Protections 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 a research project grant for which the IACUC review has been completed and approval 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 F.430 - PHS Fellowship Supplemental Form, Vertebrate Animals. 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 the NIH Grants Policy Statement Section 2.5.1: Just-in-Time Procedures.

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 Domestic and Foreign Assured institutions. **Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution.**

When an applicant organization does *not* have an Animal Welfare Assurance 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 OLAW.

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. Your entry is limited to 55 characters.

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. Your entry is limited to 55 characters.

5. Is the research performance site designated, or eligible to be designated, as a historic place?

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. Your entry is limited to 55 characters.

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, your justification must include a description of how the foreign training is more appropriate than in a domestic setting. Include reasons why the facilities, the sponsor, and/or other aspects of the proposed experience are more appropriate in a foreign 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.

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.

You may use abbreviations. Your entry is limited to 55 characters.

6.b. Optional Explanation:

This field is optional. Enter an explanation for involvement with outside entities. Your entry is limited to 55 characters.

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 font and margin specifications. 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.

Additional Instructions for Fellowship:

In addition to summarizing the research project to be conducted under the fellowship award, describe the fellowship training plan and the environment in which the research training will take place. The entire “Project Summary/Abstract” attachment is limited to 30 lines of text.

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. 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.

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 New and Early Stage Investigator Policies. 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:

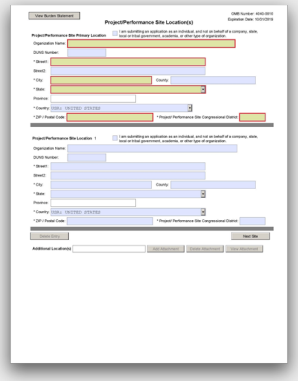
Certification Letter for Predoctoral Fellowships (F31) to Promote Diversity

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 Location(s)

Using the Project/Performance Site Location(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 off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the 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 NIH Grants Policy Statement, Section 4.1.15: Human Subjects Protections.

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 F.220 - R&R Other Project Information Form, Facilities and Resources.

"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 United States House of Representatives 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 USPS Look Up Zip Code 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 United States House of Representatives 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 USPS Look Up Zip Code website.

Additional Location(s)

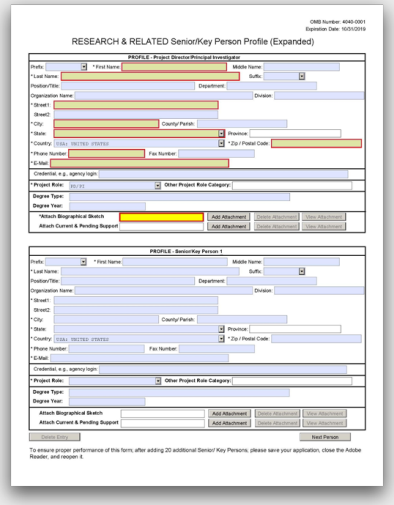
If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the "Additional Locations" section.

A format page for Additional Performance Sites can be found on NIH's Additional Performance 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 pre-populated from the SF424 (R&R) form. See instructions in F.200 - SF 424 (R&R) Form if these fields are empty.

View larger image



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/PIs: 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 e-mail 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 below 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 the NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures.

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 other significant contributors (OSCs) must include biographical sketches (biosketches).

Format:

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

Figures, tables (other than those included in the provided format pages), 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 eRA Commons, 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 Credential 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.

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; and
- 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 Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant 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.

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** graduate scientific and/or professional 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.

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 senior/key personnel. Those with a postdoctoral role should be included if they meet the NIH Glossary definition of senior/key personnel. 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). Sponsors 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 they must provide an eRA Commons username.

In addition to involving sponsors and co-sponsors, fellowship applications may also involve collaborators, consultants, advisory committee members, and contributors. These individuals are usually not considered senior/key personnel unless they contribute in a substantive, meaningful way to the project. 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/PIs:** 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 and co-sponsors, 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 above on how to complete a biographical sketch.

Attach Current & Pending Support:

Note: The terms "current and pending support," "other support," and "active and pending support" are used interchangeably.

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 the NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures 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.

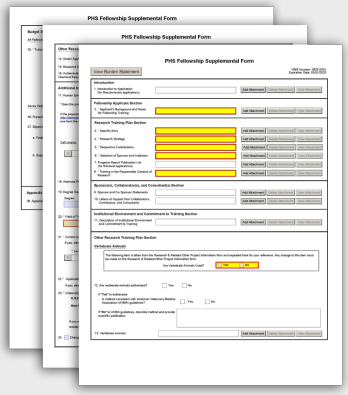
A format page for Additional Senior/Key Person Profiles can be found at NIH's Additional Senior/Key Person Form page.

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, together with the rest of your application, should include sufficient information needed for evaluation of the project and fellow, independent of any other documents (e.g., previous application). Be specific and informative, and avoid redundancies.



View larger image

Quick Links

- Introduction
- Fellowship Applicant Section
- Research Training Plan Section
- Sponsor(s), Collaborator(s), and Consultant(s) Section
- Institutional Environment and Commitment to Training Section
- 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 Roster. For AHRQ, see Research Training Staff Contacts. You are encouraged to check these websites 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 formatting, page limits, and proprietary information. 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 to Application (for Resubmission applications)

Who must complete the "Introduction to Application" 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 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:

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, and 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 your proposed 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 sponsor'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 sponsor 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 NIH Table of Page Limits, 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 NIH Table of Page Limits 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 and Innovation. Cite published experimental details in the Research Strategy and provide the full reference in F.220 - R&R Other Project Information Form, Bibliography and References Cited.

Note for Applications Proposing the Involvement of Human Subjects and/or Clinical Trials:

- Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of your proposed research, but do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information form.
- The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and children; and protection and monitoring plans.
- You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion (e.g., see Question 2.4 Inclusion of Women, Minorities, and Children).

Note for Applicants with Multiple Specific Aims: you may address the Significance and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.

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. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan attachment, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

- For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Additional information is available at the Research Methods Resources webpage.
- 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. If applicable, a full discussion on the use of select agents should appear in the Select Agent Research attachment below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed, but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.
- If you are proposing to gain clinical trial research experience (i.e., you will not be leading an independent clinical trial), briefly describe your role on the clinical trial.

As applicable, also include the following information as part of the Research Strategy, keeping within the two sections (Significance 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:

Renewal applications for individual Fellowships are rare. You should consult with your program official before preparing such an application.

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy. 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 clinical research. Use the Progress Report section to discuss, but do not duplicate information collected elsewhere in the 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 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:

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 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:

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 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 (for Renewal applications)

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 Types of Applications.

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.

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 Policy for Public 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 NIH Grants Policy Statement, Section 11.2.3.4: 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 sponsor/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 Grants Policy Statement, Section 11.2.3.4: Responsible Conduct of Research.

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. The sponsor and each co-sponsor must provide statements as described below.

Format:

Follow the page limits for Sponsor and Co-Sponsor Statements in the NIH Table of Page Limits 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 applicant's training 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.

Note for sponsors of fellowship applicants who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., but will not be leading an independent clinical trial): In addition to the information above, your statement must include the following:

- Source of funding;
- ClinicalTrials.gov Identifier (e.g., NCT87654321), if applicable; and
- A description of how your expertise is appropriate to guide the applicant in any proposed clinical trials research experience.

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 contribute to the scientific development or execution of 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 individuals in training and 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 F.220 - R&R Other Project Information Form, Facilities and Other Resources, and information provided in the Sponsor and Co-sponsor Statements 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

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 12 and 13 below.

If you have answered "Yes" for activities involving vertebrate animals: Answer Questions 12 and 13 below in consultation with both your Sponsor and AO.

12. 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.

13. 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 F.220 - R&R Other Project Information Form.

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

1. **Description of Procedures:** Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. 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.

Each of the criteria must be addressed. Failure to adequately address the criteria may negatively affect the application's impact score. In addition to the 3 criteria above, you should also:

- Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at 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
- NIH Grants Policy Statement, Section 4.1.1.1: Animal Welfare Assurance Requirements (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one)

14. 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 NIH Grants Policy Statement, Section 4.1.24.1: Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents).

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 42 CFR 73.1 as "any government agency (federal, state, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."

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

- Describe the procedures that will be used to monitor possession, use, and transfer of select agent(s).
- Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
- Describe the biocontainment resources available at all performance sites.

15. 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 Data Sharing Policy or the NIH Grants Policy Statement, Section 8.2.3.1: Data Sharing Policy.

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 the NIH Grants Policy Statement, Section 8.2.3.2: Sharing Model Organisms.

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 Grants Policy Statement, Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/Policy for Genome-Wide Association Studies (GWAS), 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 NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

16. 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

17. Human Embryonic Stem Cells

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

For additional guidance, see the NIH Grants Policy Statement, Section 4.1.13: Human Stem Cell Research.

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 hESC Registry 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.

18. 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 F.200 - SF424 (R&R) Form.

19. 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," 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 (MM/YYYY):

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

20. 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.

21. 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 Kirschstein-NRSA support while this application is pending, you must promptly report such information to the awarding component to which this application has been assigned.

22. 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, 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.

23. Citizenship

Information on Citizenship Requirements for Fellowship Applicants:

Individual Kirschstein-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."

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 posessions of the United States (e.g., American Samoa and Swains Island).

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.

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 applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, 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.

24. 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

25. 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 course work (or a degree-granting program, if applicable) that supports the research training experience and that are identified and described in the "Activities Planned Under this Award" section of the Applicant's Background and Goals for Fellowship Training attachment.

For more information:

In accordance with the NIH Grants Policy Statement, Section 11.2.9.4: Institutional Allowance, 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 Research Training and Career Development website for helpful resources and FAQs about tuition and fees.

26. 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).

27. 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

28. Appendix

The appendix policy will be changing, effective January 25, 2018. Please note that there are two sets of instructions below, based on the application due dates.

For applications submitted for due dates on or before January 24, 2018:

Refer to the FOA to determine whether there are any special appendix instructions for your application.

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into attachment #10.

Only limited items are allowed in the Appendix. 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 an Investigational New Drug (IND) application, as appropriate for the goals of the research proposed in the application

For all applications:

- Blank informed consent/assent forms
- Blank surveys, blank questionnaires, blank data collection instruments
- FOA-specified items
  - 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 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this section.

For applications submitted for due dates on or after January 25, 2018:

Refer to the FOA to determine whether there are any special appendix instructions for your application. See the updated NIH Guide Notice on the Appendix Policy.

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into attachment #10.

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:

- Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof
- Simple lists of interview questions

  Note: In your blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.
- Blank informed consent/assent forms
- Other items *only if* they are specified in the FOA as allowable appendix materials

No other items are allowed in the Appendix. Simply relocating disallowed materials to other parts of the application will result in a noncompliant application.

Some FOAs may have different instructions for the Appendix. Always follow the instructions in your FOA if they conflict with these instructions.

Note: Applications will be withdrawn and not reviewed if they do not follow the appendix requirements in these instructions or in your FOA.

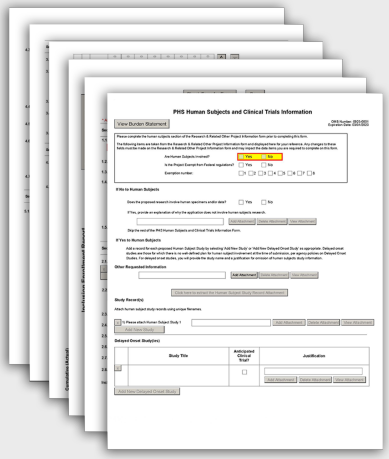
Information that expands upon or complements information provided in any section of the application - even if it is not required for the review - is not allowed in the Appendix unless it is listed in the allowed appendix materials above or in your FOA. For example, do not include material transfer agreements (MTA) in the Appendix unless otherwise specified in the FOA.

For more information:

- The NIH Guide Notice on Reminder: NIH Applications Must Be Complete and Compliant With NIH Policy and Application Instructions At Time of Submission.
- Failure of reviewers to address non-required appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review. For more information, see the NIH Grants Policy Statement, Section 2.4.2: Appeals of Initial Scientific Review.
- Appendix Policy Frequently Asked Questions

F.500 - PHS Human Subjects and Clinical Trials Information

The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis.



This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.

Read all the instructions in the Funding Opportunity Announcement (FOA) before completing this form to ensure your application meets all IC-specific criteria. If you are proposing a clinical trial, make sure your FOA accepts clinical trials (i.e., 'clinical trial required' or 'clinical trial optional').

The PHS Human Subjects and Clinical Trials Information form, together with the rest of your application, should include sufficient information for the evaluation of the project, independent of any other documents (e.g., previous application). Be specific, describe each study clearly, and avoid redundancies. Be especially careful to avoid redundancies with your research strategy.

View larger image

Quick Links

- PHS Human Subjects and Clinical Trials Information
- If No to Human Subjects
- If Yes to Human Subjects
- Other Requested Information
- Study Record(s)
- Delayed Onset Study(ies)
- Study Record: PHS Human Subjects and Clinical Trials Information
- Section 1 - Basic Information

1.1 Study Title (each study title must be unique)

1.2 Is this Study Exempt from Federal Regulations?

1.3 Exemption Number

1.4 Clinical Trial Questionnaire
1.5 Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable.
- Section 2 - Study Population Characteristics
2.1 Conditions or Focus of Study
2.2 Eligibility Criteria
2.3 Age Limits
2.4 Inclusion of Women, Minorities, and Children
2.5 Recruitment and Retention Plan
2.6 Recruitment Status
2.7 Study Timeline
2.8 Enrollment of First Subject
- Inclusion Enrollment Report(s)
- Section 3 - Protection and Monitoring Plans
3.1 Protection of Human Subjects
3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?
3.3 Data and Safety Monitoring Plan
3.4 Will a Data and Safety Monitoring Board be appointed for this study?
3.5 Overall Structure of the Study Team
- Section 4 - Protocol Synopsis
4.1 Brief Summary
4.2 Study Design
4.3 Outcome Measures
4.4 Statistical Design and Power
4.5 Subject Participation Duration
4.6 Will the study use an FDA-regulated intervention?
4.7 Dissemination Plan
- Section 5 - Other Clinical Trial-related Attachments
5.1 Other Clinical Trial-related Attachments

Complete the PHS Human Subjects and Clinical Trials Information form after you have completed the F.220 - R&R Other Project Information Form.

This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.

Who should use the PHS Human Subjects and Clinical Trials Information form:

All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question "Are human subjects involved?" on the F.220 - R&R Other Project Information Form.

If you answered "Yes" to the question "Are human subjects involved?" on the F.220 - R&R Other Project Information Form, see the "If Yes to Human Subjects" section for instructions.

If you answered "No" to the question "Are human subjects involved?" on the F.220 - R&R Other Project Information Form, see the "If No to Human Subjects" section for instructions.

Note for studies involving only the secondary use of identifiable biospecimens or data: For studies where the only involvement of human subjects is the use of identifiable biospecimens or data originally collected for another purpose, complete the PHS Human Subjects and Clinical Trials Information form with information specific to the current study and not the original collection unless the information associated with the original collection is pertinent to the proposed study. If information about the original collection is necessary, provide context and clearly distinguish between the current study and historical information.

Using the PHS Human Subjects and Clinical Trials Information form:

Follow instructions on the PHS Human Subjects and Clinical Trials Information form that are specific to your answer to the "Are Human Subjects Involved?" question on the F.220 - R&R Other Project Information Form. The PHS Human Subjects and Clinical Trials Information form allows you to add study record(s) and/or delayed onset study(ies), as applicable.

Within each Study Record: PHS Human Subjects and Clinical Trials Information, you will add detailed information at the study level. Add a separate study record for each protocol involving human subjects proposed in your application. Do not duplicate studies within your application. Each study within the application should be unique and should have a unique study title. Each study record is divided into numbered sections:

- Section 1 - Basic Information
- Section 2 – Study Population Characteristics (includes Inclusion Enrollment Report)
- Section 3 – Protection and Monitoring Plans
- Section 4 – Protocol Synopsis
- Section 5 – Other Clinical Trial-related Attachments

Note: The PHS Human Subjects and Clinical Trials Information form will capture detailed information at the study level. Although you are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form in your discussion of the Research Strategy, do not duplicate information between the Research Strategy attachment and the PHS Human Subjects and Clinical Trials Information form.

The PHS Human Subjects and Clinical Trials Information form is dynamic and may eliminate sections that are not relevant to your application. The dynamic form behavior may not be enabled on all submission methods.

Additional Instructions for Fellowship:

Fellowship applicants are permitted to conduct research involving human subjects; however, they are NOT permitted to lead an independent clinical trial.

Fellowship applicants who are not proposing a clinical trial: Follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form.

Fellowship applicants who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Fellowship instructions where they are given. *Make sure you are applying to a FOA that does NOT allow independent clinical trials, but that does encourage a clinical trial research experience led by a sponsor/co-sponsor (or another member of the mentoring team)*. Additionally, the sponsor or co-sponsor is required to include a statement to document leadership of the clinical trial. The statement must include the following:

- Source of funding;
- ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable; and
- A description of how the sponsor or co-sponsor's expertise is appropriate to guide the applicant in any proposed clinical trials research experience.

This statement must be included in the "Sponsor and Co-Sponsor Statements" attachment of the F.430 - PHS Fellowship Supplemental Form.

Applicants must follow all policies and requirements related to formatting, proprietary information, human subjects, and clinical trials. See the following pages for more information:

- Format Attachments
- 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
- Research Involving Human Subjects
- NIH's Clinical Trials website

Note: There are no page limits for any attachments in the PHS Human Subjects and Clinical Trials Information form.

PHS Human Subjects and Clinical Trials Information

Applicants must complete the human subjects questions on the F.220 - R&R Other Project Information Form prior to completing this form.

Are Human Subjects Involved? Yes/No

This field is pre-populated from the F.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the F.220 - R&R Other Project Information Form.

Is the Project Exempt from Federal regulations? Yes/No

This field is pre-populated from the F.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the F.220 - R&R Other

Project Information Form.

Exemption number: 1, 2, 3, 4, 5, 6, 7, 8

This field is pre-populated from the F.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the F.220 – R&R Other Project Information Form. **You should not have selected exemption 7 or 8, as these are not yet being used.**

Note: If you change your answer to the "Are Human Subjects Involved" question on the F.220 - R&R Other Project Information Form after you have started entering information into the PHS Human Subjects and Clinical Trials Information form, your data in the PHS Human Subjects and Clinical Trials Information form may be lost.

If No to Human Subjects

If you answered "No" to the question "Are Human Subjects Involved?" on the F.220 - R&R Other Project Information Form, answer the following question(s) about the use of human specimens and/or human data.

Does the proposed research involve human specimens and/or data?

Select "Yes" or "No" to indicate whether the proposed research involves human specimens and/or data.

Applications involving the use of human specimens or data may not be considered to be research involving human subjects, depending on the details of the materials to be used. To help determine whether your research is classified as human subjects research, refer to the Research Involving Private Information or Biological Specimens flowchart.

Note: If you answered "No" to the "Does the proposed research involve human specimens and/or data?" question, skip the rest of the PHS Human Subjects and Clinical Trials Information form unless otherwise directed by your FOA.

If Yes, provide an explanation of why the application does not involve human subjects research.

If you answered "Yes" to the "Does the proposed research involve human specimens and/or data?" question, you must provide a justification for your claim that no human subjects are involved.

Attach the justification as a PDF file. See NIH's Format Attachments page.

This justification should include:

- information on who is providing the data/biological specimens and their role in the proposed research;
- a description of the identifiers that will be associated with the human specimens and data;
- a list of who has access to subjects' identities; and
- information about the manner in which the privacy of research participants and confidentiality of data will be protected.

Note: Once you have attached the justification, skip the rest of the PHS Human Subjects and Clinical Trials Information form unless otherwise directed by your FOA.

If Yes to Human Subjects

If you answered "Yes" to the question "Are Human Subjects Involved?" on the F.220 - R&R Other Project Information Form, add a study record for each proposed study involving human subjects by selecting "Add New Study" or "Add New Delayed Onset Study," as appropriate.

Other Requested Information

Who may provide Other Requested Information:

Follow the instructions below and any instructions in your FOA to determine whether you are permitted to include the "Other Requested Information" attachment.

Format:

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

Content:

Content is limited to what is described in your FOA or in these instructions. Do not use the "Other Requested Information" attachment to include any other information.

Renewal applications: When preparing a renewal (or resubmission of a renewal), you can provide a list of ongoing studies or ClinicalTrials.gov identifiers (e.g., NCT87654321).

Study Record(s)

Adding Study Record Attachment(s):

Add a study record for each proposed study involving human subjects. If your study is a delayed onset study, see the instructions for Delayed Onset Study(ies).

For all submission methods, the Study Record is used to collect human subjects study data. **Note: The steps to add a Study Record attachment(s) may vary with the submission method**. For example, from the ASSIST Human Subjects and Clinical Trials tab, use the 'Add New Study' button to access the data entry screens to enter study record information directly into ASSIST. With other submission methods, you may have to extract a blank copy of the Study Record, complete it offline, and then attach it to your application.

The PHS Human Subjects and Clinical Trials Information form accommodates up to 150 separate Study Records.

Format:

All attachments must be PDF files. The study records are already fillable PDFs when extracted. Do not alter the format of the study record file. Use unique file names for each human subject study record.

Content:

Follow the instructions in the "Study Record: PHS Human Subjects and Clinical Trials Information" section below.

Delayed Onset Study(ies)

If any of your human subjects studies meet the agency definition of "delayed onset human subject study," enter the information as instructed below. For any study that you include as a delayed onset study in this section, do not fill out a full study record, as the delayed onset record is sufficient.

Notes on delayed onset studies:

- Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).
- If you have multiple delayed onset studies, you can include them together in a single Delayed Onset Study.

Study Title

This field is required.

The Study Title can have a maximum of 600 characters.

Enter a brief, unique title that describes the study the participants will be involved in. Each study within your application must have a unique Study Title. The first 150 characters will display in the application image bookmarks.

Note on multiple delayed onset studies: If you are including multiple delayed onset studies in one delayed onset study entry, you may enter "Multiple Delayed Onset Studies" as the title of this record.

Anticipated Clinical Trial?

This field is required.

Check this box if you anticipate that this study will be a clinical trial. For help determining whether your study meets the definition of clinical trial, see the Clinical Trial Questionnaire below.

Read your FOA carefully to determine whether clinical trials are allowed in your application.

Note on multiple delayed onset studies: If you are including multiple delayed onset studies in one delayed onset study entry, and you anticipate that any of these studies will be a clinical trial, check the "Anticipated Clinical Trial?" checkbox.

Additional Instructions for Fellowship:

Do not check the "Anticipated Clinical Trial?" box. Fellowship FOAs do not allow independent clinical trials.

Justification Attachment

This attachment is required.

Attach the justification as a PDF file. See NIH's Format Attachments page.

- All delayed onset studies must provide a justification explaining why human subjects study information is not available at the time of application.
- If NIH's Single Institutional Review Board (sIRB) policy will apply to your study, this justification must also include information regarding how the study will comply with the

policy and state that you will provide a single IRB plan prior to initiating any multi-site study.

- If NIH's Policy on the Dissemination of NIH-Funded Clinical Trial Information will apply to your study, this justification must also include the dissemination plan.

Note on multiple delayed onset studies: If you are including more than one delayed onset study in any given delayed onset study entry, address all the included studies in a single justification attachment.

Study Record: PHS Human Subjects and Clinical Trials Information

Section 1 - Basic Information

Who must complete "Section 1 – Basic Information:"

"Section 1 – Basic Information" is required for all studies involving human subjects.

1.1 Study Title (each study title must be unique)

The "Study Title" field is required.

The Study Title can have a maximum of 600 characters.

Enter a brief title that describes the study the participants will be involved in. If there is more than one study (i.e., you are including more than one study record and/or delayed onset study in your application), each one must have a unique study title. The first 150 characters will display in the bookmarks of the application image.

Note: When registering a clinical trial in ClinicalTrials.gov, all study titles across your organization must be unique.

1.2 Is this Study Exempt from Federal Regulations?

An answer to the "Is this Study Exempt from Federal Regulations?" question is required.

Indicate whether the study is exempt from Federal regulations for the Protection of Human Subjects.

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

1.3 Exemption Number

The "Exemption Number" field is required if you selected "Yes" to the "Is this Study Exempt from Federal Regulations?" question.

Select the appropriate exemption number(s) for this particular study. Multiple selections are permitted. **Do not select exemption 7 or 8, as these are not yet being used.** Regardless of whether these exemptions may apply to you in the future, you must fill out your application following the instructions below. The instructions do not take exemption 7 and 8 into account.

For more information:

The 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.
- See the Frequently Asked Questions from Applicants section on Exemptions.

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.

1.4 Clinical Trial Questionnaire

The Clinical Trial Questionnaire is required.

Note for mechanistic studies: Many mechanistic studies (i.e., those designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention) meet the NIH definition of a clinical trial.

Answer "Yes" or "No" to the following questions to determine whether this study involves a clinical trial. Answer the following questions based only on the study you are describing in this study record.

1.4.a. Does the study involve human participants? Yes/No

1.4.b. Are the participants prospectively assigned to an intervention? Yes/No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? Yes/No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes/No

If you answered "Yes" to all the questions in the Clinical Trial Questionnaire, this study meets the definition of a clinical trial.

Refer to the table below for information about what sections of this form are required, based on your answers to Question 1.4 "Clinical Trial Questionnaire."

Form Section	If you answered "yes" to all the questions in the Clinical Trial Questionnaire	If you answered "no" to any of the questions in the Clinical Trial Questionnaire
Section 2 - Study Population Characteristics	Required	Required

Form Section	If you answered "yes" to all the questions in the Clinical Trial Questionnaire	If you answered "no" to any of the questions in the Clinical Trial Questionnaire
Section 3 - Protection and Monitoring Plans	Required	Required
Section 4 - Protocol Synopsis	Required	Do not complete
Section 5 - Other Clinical Trial-related Attachments	Required if specified in the FOA	Do not complete

Additional Instructions for Fellowship:

Fellowship applicants who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): Even if you answered "Yes" to all the questions in the Clinical Trial Questionnaire, only certain fields of the PHS Human Subjects and Clinical Trials Information form are required (and other fields are not allowed) because the study is not an independent clinical trial. Do not provide information in sections 4 or 5 or your application will be rejected.

You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Fellowship instructions where they are given.

For more information:

- NIH Glossary's definition of an NIH-defined clinical trial
- NIH's Definition of a Clinical Trial page
- NIH Definition of Clinical Trials Case Studies page
- FAQs on the NIH Clinical Trial Definition
- NIH's decision tool will help determine whether your human subjects research study is an NIH-defined clinical trial
- Your study may also be subject to additional regulations. Read NIH's Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov.

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

If a clinical trial has already been entered into ClinicalTrials.gov, enter the ClinicalTrials.gov identifier (e.g., NCT87654321) for this trial.

If you are building on an existing study (e.g., ancillary study), enter the ClinicalTrials.gov identifier only for the ancillary study, not the parent study.

Section 2 - Study Population Characteristics

Who must complete "Section 2 - Study Population Characteristics:"

All of "Section 2 – Study Population Characteristics" is required for all human subjects studies unless either or both of the following apply to you:

- If you selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question, then "Section 2 – Study Population Characteristics" is not required.
- If you selected "**No**" to the "1.4.a. Does the study involve human participants?" question, then certain questions in "Section 2 – Study Population Characteristics" are not required, as noted in the individual field instructions below.

2.1 Conditions or Focus of Study

At least 1 entry is required, and up to 20 entries are allowed. Each entry is limited to 255 characters.

Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH) so the application can be categorized. Include an entry for each condition.

2.2 Eligibility Criteria

List the study's inclusion and exclusion criteria. To provide a bulleted list, use a dash (or other character) followed by a space ("- ") at the start of each bullet. Be sure to check the formatting in the assembled application image. Further explanation or justification should be included in the Recruitment and Retention plan.

Your text entry is limited to 15,000 characters.

2.3 Age Limits

Minimum Age

Enter the numerical value for the minimum age a potential participant can be to be eligible for the study. Provide the relevant units of time (i.e., years, months, weeks, days, hours, or minutes). If there is no lower limit or no lower limit is known, enter "N/A (No Limit)" and do not enter a unit of time.

Maximum Age

Enter the numerical value for the maximum age a potential participant can be to be eligible for the study. Provide the relevant units of time (i.e., years, months, weeks, days, hours, or minutes). If there is no upper limit or no upper limit is known, enter "N/A (No Limit)" and do not enter a unit of time.

2.4 Inclusion of Women, Minorities, and Children

Format:

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

Content:

Organize your attachment into two sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – "Inclusion of Women and Minorities" and "Inclusion of Children." Also include any additional information requested in the FOA.

You will also have to complete an Inclusion Enrollment Report (IER). Note that you may need to include multiple IERs for each study. Refer to the instructions for the IER below for more information.

1. Inclusion of Women and Minorities

Address the following points:

- Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
- Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
- Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
- Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page for more information.

Existing Datasets or Resources. If you will use an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

NIH-Defined Phase III Clinical Trials. If the proposed research includes an NIH-Defined Phase III Clinical Trial, the "Inclusion of Women, Minorities, and Children" attachment MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial. See the instructions for "Valid Analysis" and "Plans to test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups" below.

Additional information about valid analysis is available on the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research page.

Valid Analysis (for NIH-Defined Phase III Clinical Trials only):

Address the following issues for ensuring valid analyses:

- Inclusive eligibility criteria – in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
- Allocation of study participants of both sexes/genders and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization;
- Unbiased evaluation of the outcome(s) of study participants; and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that such differences exist.

Plan to Test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups (for NIH-Defined Phase III Clinical Trials only):

Applicants also should address whether they plan to test for differences in effect among sex/gender, racial, and/or ethnic groups and why such testing is or is not appropriate.

This plan must include selection and discussion of one of the following analysis plans:

- Plans to conduct analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among one or more subgroups, or
- Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or
- Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

2. Inclusion of Children

For the purposes of the Inclusion of Children, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group (e.g., older adults) should be justified in this section. In addition, address the following points:

- Children are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether children (as a whole or a subset of individuals under 18) will be included or excluded. If children will be included, include a rationale for selecting a specific age range of children, if relevant. If children will be excluded, provide a rationale for exclusion. See the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects for additional information about circumstances that may justify the exclusion of children.
- Include a description of the expertise of the investigative team for working with children of the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

- When children are involved in research, the policies under HHS' 45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research apply and must be addressed in the Protection of Human Subjects attachment.

For more information, see:

- NIH's Policy Implementation Page on the Inclusion of Women and Minorities
- NIH's Policy Implementation Page on the Inclusion of Children
- HHS' 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Fetuses, and Neonates
- HHS' 45 CFR 46 Subpart D – Additional Protections for Children
- NIH Grants Policy Statement, Section 4.1.15.7: Inclusion of Children as Subjects in Clinical Research
- NIH Grants Policy Statement, Section 4.1.15.8: Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

2.5 Recruitment and Retention Plan

Who must complete the "Recruitment and Retention Plan" attachment:

The "Recruitment and Retention Plan" attachment is required unless either or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.
- You selected "**No**" to the "1.4.a. Does the study involve human participants?" question.

Format:

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

Content:

Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.

2.6. Recruitment Status

Who must complete the "Recruitment Status" question:

The "Recruitment Status" question is required unless either or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.
- You selected "**No**" to the "1.4.a. Does the study involve human participants?" question.

Content:

From the dropdown menu, select a single "Recruitment Status" that best describes the proposed study, based upon the status of the individual sites. If any facility in a multi-site study has an

individual site status of "recruiting," then choose "recruiting" for this question. Only one selection is allowed. Choose from the following options:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated (Halted Prematurely)
- Withdrawn (No Participants Enrolled)

2.7. Study Timeline

Who must complete the "Study Timeline" attachment:

The "Study Timeline" attachment is required unless either or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.
- You selected "**No**" to the "1.4.a. Does the study involve human participants?" question.

Format:

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

Content:

Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates.

Note: Additional milestones or timelines may be requested as just-in-time information or post-award.

2.8. Enrollment of First Subject

Who must complete the "Enrollment of First Subject" question:

The "Enrollment of First Subject" question is required unless either or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.
- You selected "**No**" to the "1.4.a. Does the study involve human participants?" question.

Content:

Enter the date (MM/DD/YYYY) of the enrollment of the first subject into the study. From the dropdown menu, select whether this date is anticipated or actual.

Inclusion Enrollment Report(s)

Who must complete the Inclusion Enrollment Report(s):

An Inclusion Enrollment Report is required for all human subjects studies unless, on Question 1.3 "Exemption Number," you selected only Exemption 4 and no other exemptions.

Using the Inclusion Enrollment Report:

Each proposed study, unless it falls under Exemption 4, must contain at least one Inclusion Enrollment Report (IER). However, more than one IER per study is allowed.

Once you have added an IER for a given study, you may edit, remove, or view it.

Note: The IER format should NOT be used for collecting data from study participants.

Note: You can add a maximum of 20 IERs per study record. These can be a combination of planned and cumulative reports.

Multi-site studies: Generally, if the application includes a study recruiting subjects at more than one site/location, investigators may create one IER or separate, multiple IERs to enable reporting by study or by site, depending on the scientific goals of the study and whether monitoring of inclusion enrollment would benefit from being combined or separated. At a minimum, participants enrolled at non-U.S. sites must be reported separately from participants enrolled at U.S. sites, even if they are part of the same study. Please review the FOA to determine whether there are any other specific requirements about how to complete the IER.

Duplicative Inclusion Reports: It is important that the IER for a given study be associated with only one application and be provided only once in a given application (e.g., do not submit the same IER on both the data coordinating center and the research site). If submitting individual application(s) as part of a network or set of linked applications, please provide the IER with the individual site applications unless otherwise directed by the FOA.

Renewal applications: When preparing a renewal (or resubmission of a renewal), investigators should provide a narrative description regarding the cumulative enrollment from the previous funding period (s) as part of the progress report section of the research strategy attachment in the application. The IER should NOT be used for this purpose. If a given study will continue with the same enrollment or additional enrollment, or if new studies are proposed, provide a new IER for each as described in the instructions below.

Resubmission applications: If IERs were provided in the initial submission application, and if those studies will be part of the resubmission application, complete the IER and submit again with the resubmission application, regardless of whether the enrollment has changed or not. Also, provide any new (additional) IERs.

Revision applications: Provide an IER if new studies are planned as part of the Revision and they meet the NIH definition for clinical research.

For more information:

Refer to the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page.

1. Using an Existing Dataset or Resource?

The "Using an Existing Dataset or Resource" question is required.

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

For additional guidance on what is considered an existing dataset, refer to the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

2. Enrollment Location Type (Domestic/Foreign)

The "Enrollment Location Type" field is required.

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

For additional guidance on how to complete the IER if you will be working with non-U.S. populations, refer to these FAQs on Monitoring Inclusion in Non-US Research Participants.

3. Enrollment Country(ies)

The "Enrollment Country(ies)" field is optional.

Indicate the enrollment country or countries for the participants. Multiple U.S. sites can be reported together in one IER. Foreign countries can be reported together in one IER. However, you must use separate IERs for U.S. and non-U.S. sites. You can add up to 200 countries per IER.

4. Enrollment Location(s)

The "Enrollment Location(s)" field is optional.

Indicate the type of enrollment location (e.g., hospital, university, or research center), not the name of the enrollment location.

Enrollment locations are typically where the research is conducted, and can be different from the recruitment site.

5. Comments

Your comments are limited to 500 characters.

Enter information you wish to provide about this IER. This includes, but is not limited to, addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied. If inclusion monitoring is conducted on another study or NIH grant (e.g., data coordinating center or research site), please indicate here.

Revision applications: If there are no updates to the IER(s) in your original grant application, do not include an IER in your Revision application. Instead, provide a comment in this field to the effect that previous IER(s) are still applicable. If you are revising the IER(s) in your original grant application, provide a comment here to that effect.

Planned

Who must complete planned enrollment tables:

You must enter planned enrollment counts if your proposed study will **not** use an existing dataset or resource. Planned enrollment generally means that individuals will be recruited into the study and/or that individuals have already been recruited and continue to be part of the study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

For more information on racial categories, see the NIH Glossary definition of Racial Categories.

For more information on ethnic categories, see the NIH Glossary definition of Ethnic Categories.

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.

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.

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.

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.

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.

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.

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. The "Total" fields in the right column will be automatically calculated to total all individuals.

Cumulative (Actual)

Who must complete cumulative (actual) enrollment tables:

You must enter cumulative enrollment counts if your proposed study will use an existing dataset or resource.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources.

For more information on racial categories, see the NIH Glossary definition of Racial Categories.

For more information on ethnic categories, see the NIH Glossary definition of Ethnic Categories.

Racial Categories

American Indian/Alaska Native:

These fields are required.

Enter the number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Not Hispanic or Latino. Enter the 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 as needed (i.e., race and/or ethnicity is unknown).

Asian:

These fields are required.

Enter the 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 as needed (i.e., race and/or ethnicity is unknown).

Native Hawaiian or Other Pacific Islander:

These fields are required.

Enter the 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 as needed (i.e., race and/or ethnicity is unknown).

Black or African American:

These fields are required.

Enter the 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 as needed (i.e., race and/or ethnicity is unknown).

White:

These fields are required.

Enter the 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 as needed (i.e., race and/or ethnicity is unknown).

More than One Race:

These fields are required.

Enter the 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 as needed (i.e., race and/or ethnicity is unknown).

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 as needed (i.e., race and/or ethnicity is unknown).

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 as needed (i.e., race and/or ethnicity is unknown). The "Total" fields in the right column will be automatically calculated to total all individuals.

Section 3 – Protection And Monitoring Plans

Who must complete "Section 3 – Protection and Monitoring Plans:"

All of "Section 3 – Protection and Monitoring Plans" is required for all studies involving human subjects, unless otherwise noted.

3.1 Protection of Human Subjects

The "Protection of Human Subjects" attachment is required.

Format:

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

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

For Human Subjects Research Claiming Exemptions: If you are claiming that your human subjects research falls under any exemptions, justify why the research meets the criteria for the exemption(s) that you have claimed. This justification should explain how the proposed research meets the criteria for the exemption claimed. Do not merely repeat the criteria or definitions themselves.

For Studies that involve Non-Exempt Human Subjects Research: For any proposed non-exempt study involving human subjects, NIH requires a Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to Research Participants and Others, and Importance of the Knowledge to be Gained. Also include any additional information requested in the FOA.

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

- Briefly describe the overall study design.
- Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.

b. Study Procedures, Materials, and Potential Risks

- Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.

- For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
- Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
- Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

- Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
    - **For research involving children:** If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
- If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so.

b. Protections Against Risk

- Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.
- Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.

c. Vulnerable Subjects, if relevant to your study

Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).

Pregnant Women, Fetuses, and Neonates or Children

If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.

- HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
- HHS' Subpart D - Additional Protections for Children
- OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

Prisoners

If the study involves vulnerable subjects subject to additional protections under Subpart C (prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research.

Refer to HHS regulations, and OHRP guidance:

- HHS' Subpart C - Additional Protections Pertaining to Prisoners as Subjects
- OHRP Subpart C Guidance on Involvement of Prisoners in Research

3. Potential Benefits of the Proposed Research to Research Participants and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
- **Note:** Financial compensation of subjects should not be presented as a benefit of participation in research.

4. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

For more information:

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

3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

Select "Yes" or "No" to indicate whether this is a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site.

Select "N/A" only if any of the following apply (do not select "N/A" if none of the following apply):

- You answered "Yes" to "Question 1.2 Is this Study Exempt from Federal Regulations? (Yes/No)"
- You are a career development applicant
- You are a training applicant
- You are a fellowship applicant

Applicants who check "Yes" are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research.

Note: The NIH sIRB policy applies to participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies are not expected to follow this policy.

Additional Instructions for Fellowship:

Check "N/A," as the sIRB policy does not apply to fellowship awards.

For more information:

- HHS regulations and requirements for the Protections of Human Subjects can be found at 45 CFR 46.
- See NIH's Single IRB Policy for Multi-site Research for more information.

If yes, describe the single IRB plan

Format:

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

Although one sIRB attachment per application is sufficient, you must include a file for each study within your application. All file names within your application must be unique. You may either attach the same sIRB plan (with different file names) to different studies or attach a file that refers to the sIRB plan in another study within your application. For example, you may attach a file that says "See sIRB plan in the 'My Unique Study Name' study."

Content:

The sIRB plan should include the following elements:

- Describe how you will comply with the NIH Policy on the Use of sIRB for Multi-Site Research.
- Provide the name of the IRB that will serve as the sIRB of record.
- Indicate that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
- Briefly describe how communication between sites and the sIRB will be handled.
- Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- **Note:** Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- **Note:** If your human subjects study meets the agency definition of "Delayed Onset," include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study in the delayed onset study justification.

For Studies with Legal-, Regulatory-, or Policy-based Claims for Exception as described by the sIRB Policy: Indicate that review by an sIRB will not be possible for all or some sites (specify which sites) because local IRB review is required by an existing federal/state/tribal law or policy. Include a specific citation to the relevant law, policy, or regulation.

For sites requesting an exception based on compelling justification: Indicate which site(s) is requesting an exception to the use of the sIRB and provide compelling justification based on ethical or human subjects protection issues or other well-justified reasons. NIH will determine whether to grant an exception following an assessment of the need. **Note:** If you intend to request an exception to the sIRB policy based on compelling justification, do not account for this exception in your proposed budget. The proposed budget must reflect any necessary sIRB costs without an exception (i.e., applicants should not assume that an exception will be granted when considering what sIRB costs to include in the budget).

For more information:

- NIH Office of Science Policy Clinical Research IRB Review page
- FAQs on NIH Policy on the Use of a Single IRB for Multi-Site Research Costs
- FAQs on Implementation of the sIRB policy
- NIH Guide Notice on the Final NIH Policy on sIRB

3.3 Data and Safety Monitoring Plan

A "Data and Safety Monitoring Plan" attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." The "Data and Safety Monitoring Plan" attachment is optional for all other human subjects research.

For human subjects research that does not involve a clinical trial: Your study, although it is not a clinical trial, may have significant risks to participants, and it may be appropriate to include a data and safety monitoring plan. If you choose to include a data and safety monitoring plan, you may follow the content criteria listed below, as appropriate.

Format:

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

Content:

Additional Instructions for Fellowship:

Fellowship applicants who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): Include only the following information in your data and safety monitoring plan (i.e., do not follow the standard instructions for the data and safety monitoring plan):

- The names of the individual(s) or group that will be responsible for trial monitoring (i.e., the lead investigator of clinical trial)
- If applicable, the name of an independent safety monitor or a data and safety monitoring board

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
  - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
  - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
  - Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
  - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

For more information:

- NIH Grants Policy Statement, Section 4.1.15.6: Data and Safety Monitoring

3.4 Will a Data and Safety Monitoring Board be appointed for this study?

The "Data Safety and Monitoring Board" question is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." This question is optional for all other human subjects research.

Check the appropriate box to indicate whether a Data Safety and Monitoring Board (DSMB) will be appointed for this study.

3.5 Overall Structure of the Study Team

The "Overall Structure of the Study Team" attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." This question is optional for all other human

subjects research.

Format:

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

Content:

Provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.

Note: Do not include study team members' individual professional experiences (i.e., biosketch information).

Section 4 – Protocol Synopsis

Who must complete "Section 4 – Protocol Synopsis:"

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" All the questions in the "Protocol Synopsis" section are required.

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section or your application will be rejected.

Additional Instructions for Fellowship:

Do not provide information in "Section 4 - Protocol Synopsis" or your application will be rejected.

4.1 Brief Summary

Enter a brief description of objectives of the protocol, including the primary and secondary endpoints. The Brief Summary is limited to 5,000 characters.

4.2. Study Design

4.2.a. Narrative Study Description

Enter a narrative description of the protocol. Studies differ considerably in the methods used to assign participants and deliver interventions. Applicants will need to show that their methods are appropriate given their plans for assignment of participants, delivery of interventions, and data collection and analysis.

Describe how participants are assigned in groups or clusters (e.g., families, providers, clinics, schools, communities), and/or when interventions are delivered to groups or clusters, and/or how and when observations on individual participants are analyzed, and any special methods that are required for analysis and sample size.

The narrative description is limited to 32,000 characters.

For more information on assigning participants to groups, see the Research Methods Resources webpage.

4.2.b. Primary Purpose

Enter or select from the dropdown menu a single "Primary Purpose" that best describes the clinical trial. Choose from the following options:

- Treatment
- Prevention
- Diagnostics
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

4.2.c. Interventions

Complete the "Interventions" fields for each intervention to be used in your proposed protocol. If an arm of the study to which subjects will be assigned (as discussed in 4.2.a. Narrative Study Description) includes more than one intervention (e.g., drug plus educational intervention), complete this section for each intervention. You can add up to 20 interventions.

Intervention Type: Enter or select from the dropdown menu the intervention type the clinical trial will administer during the proposed award. Choose from the following options:

- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell, and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Combination Product
- Diagnostic Test
- Other

Name: Enter the name of the intervention. The name must be unique within each study record. The name is limited to 200 characters.

Description: Enter a description of the intervention. The description is limited to 1,000 characters.

4.2.d. Study Phase

Enter or select from the dropdown menu a "Study Phase" that best describes the clinical trial. If your study involves a device, choose "Other."

Choose from the following options:

- Early Phase 1 (or Phase 0)
- Phase 1
- Phase 1/2
- Phase 2
- Phase 2/3
- Phase 3
- Phase 4
- Other (If you select “Other,” provide a description in the space provided. Your response is limited to 255 characters.)

Is this an NIH-defined Phase III clinical trial? Yes/No

Select "Yes" or "No" to indicate whether the study includes an NIH-defined Phase III clinical trial.

4.2.e. Intervention Model

Enter or select from the dropdown menu a single "Intervention Model" that best describes the clinical trial. If you select “Other,” provide a description in the space provided. Choose from the following options:

- Single Group
- Parallel
- Cross-Over
- Factorial
- Sequential
- Other (If you select “Other,” provide a description in the space provided. Your response is limited to 255 characters.)

4.2.f. Masking

Select "Yes" or "No" to indicate whether the protocol uses masking. Note that masking is also referred to as “blinding.”

If you answered “Yes” to the “Masking” question, select one or more types of masking that best describes the protocol. Choose from the following options:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor

4.2.g. Allocation

Enter or select from the dropdown menu a single "Allocation" that best describes how subjects will be assigned in your protocol. If allocation is not applicable to your clinical trial, select “N/A” (e.g., for a single-arm trial). Choose from the following options:

- N/A
- Randomized

- Non-randomized

4.3. Outcome Measures

Complete the "Outcome Measures" fields for each primary, secondary, and other important measures to be collected during your proposed clinical trial. You may have more than one primary outcome measure, and you can add up to 50 outcome measures.

Name: Enter the name of the individual outcome measure. The outcome measure must be unique within each study record.

Type: Enter or select from the dropdown menu the type of the outcome measure. Choose from the following options:

- Primary – select this option for the outcome measures specified in your protocol that are of greatest importance to your study
- Secondary – select this option for outcome measures specified in your protocol that are of lesser importance to your study than your primary outcomes
- Other – select this option for additional key outcome measures used to evaluate the intervention.

Time Frame: Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment).

Brief Description: Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. Your description is limited to 999 characters.

4.4. Statistical Design and Power

Format:

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

Content:

Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use with respect to each outcome measure you listed in 4.3 Outcome Measures.

4.5 Subject Participation Duration

Enter the time (e.g., in months) it will take for each individual participant to complete all study visits. If the participation duration is unknown or not applicable, write "unknown" or "not applicable." The subject participation duration is limited to 255 characters.

4.6 Will the study use an FDA-regulated intervention?

Select "Yes" or "No" to indicate whether the study will use an FDA-regulated intervention (see the definition of "FDA Regulated Intervention" under the Oversight section of the ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies page).

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status:

This attachment is required if you answered "Yes" to the "Will the study use an FDA-regulated intervention?" question.

Format:

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

Content:

Describe the availability of study agents and support for the acquisition and administration of the study agent(s). Please indicate the IND/IDE status of the study agent, if applicable, and whether the investigators have had any interactions with the FDA. If the study agent currently has an IND/IDE number, provide that information. **Note:** The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award.

4.7 Dissemination Plan

Format:

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

Although one Dissemination Plan per application is sufficient, you must include a file for each study within your application. All file names within your application must be unique. You may either attach the same Dissemination Plan to different studies or attach a file that refers to the Dissemination Plan in another study within your application. For example, you may attach a file that says "See Dissemination Plan in the 'My Unique Study Name' study."

Content:

Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met. The plan must contain sufficient information to assure the following:

- the applicant will ensure that clinical trial(s) under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy;
- informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
- the recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

Note: Do not include informed consent documents in your application.

Note: If your human subjects study meets the definition of "Delayed Onset," include the dissemination plan in the delayed onset study justification.

For more information:

See the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information.

Section 5 – Other Clinical Trial-related Attachments

Who must complete "Section 5 – Other Clinical Trial-related Attachments:"

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" Include an attachment only if your FOA specifies that an attachment(s) is required or permitted; otherwise, do not include any Other Clinical Trial-related attachments.

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section or your application will be rejected.

Additional Instructions for Fellowship:

Fellowship applicants proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial: Do not provide information in "Section 5 – Other Clinical Trial-related Attachments" or your application will be rejected.

5.1 Other Clinical Trial-related Attachments

Format:

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

A maximum of 10 PDF attachments is allowed in the "Other Clinical Trial-related Attachments" section.

Content:

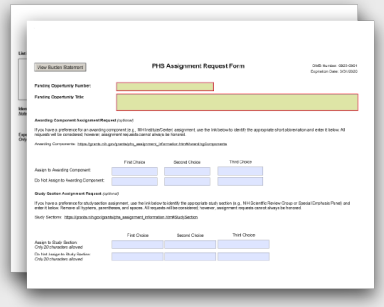
Provide additional trial-related information only if your FOA specifically requests it.

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.


View larger image

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 awarding components such as 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 award component is pre-determined and assignment requests cannot be honored. Applications are assigned based on relevance of your application to an individual awarding component mission and scientific interests in addition to administrative requirements such as IC participation in the funding opportunity announcement used to submit your application.

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:

You may enter up to three preferences for primary assignment in the boxes in the “Assign to Awarding Component” row. Use the column labeled “First Choice” to enter your first choice. Your first choice will be considered first, followed by your second choice, etc. Any of your choices may be assigned.

Do Not Assign to Awarding Component:

You may 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 “First Choice” 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 text formatted like “ZRG1 HDM-R (11) B” for an SBIR/STTR panel. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request. All parts of the short abbreviation are important for accuracy. Freeform text (such as "special emphasis panel" or "member conflict SEP") should not be entered.

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. A list of all NIH SRGs and SEPs is also available.

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:

You may 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 “First Choice” to enter your first choice. Your first choice will be considered first, followed by your second choice, etc. Any of your choices may be assigned.

Note: this information is not applicable if you are submitting an application to an RFA.

Do Not Assign to Study Section:

You may 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 “First Choice” to enter your first choice.

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

You may list specific individuals, if any, 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 correctly identify the individual. Be prepared to provide additional

information to the SRO if needed. 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)

You may 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 Person Profile (Expanded) Form
- PHS Fellowship Supplemental Form
- PHS Human Subjects and Clinical Trials Information
- PHS Assignment Request Form

SF 424 (R&R) Form

View Burden Statement

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE
State Application Identifier

1. TYPE OF SUBMISSION
Pre-application Application Changed/Corrected Application

4. a. Federal Identifier
b. Agency Routing Identifier
c. Previous Grants.gov Tracking ID

2. DATE SUBMITTED
Applicant Identifier

5. APPLICANT INFORMATION
Organizational DUNS:
Legal Name:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:

Person to be contacted on matters involving this application
Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

6. EMPLOYER IDENTIFICATION *(EIN) or (TIN):*

7. TYPE OF APPLICANT: Please select one of the following
Other (Specify):
Small Business Organization Type Women Owned Socially and Economically Disadvantaged

8. TYPE OF APPLICATION:
New Resubmission
Renewal Continuation Revision

If Revision, mark appropriate box(es).
A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration
E. Other (specify):

Is this application being submitted to other agencies? Yes No What other Agencies?

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE **Page 2**

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization Name:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested
b. Total Non-Federal Funds
c. Total Federal & Non-Federal Funds
d. Estimated Program Income

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR
☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

☐ **I agree**

**The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory 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 / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

Signature of Authorized Representative **Date Signed**

20. Pre-application Add Attachment | Delete Attachment | View Attachment

21. Cover Letter Attachment Add Attachment | Delete Attachment | View Attachment

R&R Other Project Information Form

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

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

IRB Approval Date:

Human Subject Assurance Number:

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number:

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

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No

4.b. If yes, please explain:

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

4.d. If yes, please explain:

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

5.a. If yes, please explain:

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

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. Project Summary/Abstract Add Attachment | Delete Attachment | View Attachment

8. Project Narrative Add Attachment | Delete Attachment | View Attachment

9. Bibliography & References Cited Add Attachment | Delete Attachment | View Attachment

10. Facilities & Other Resources Add Attachment | Delete Attachment | View Attachment

11. Equipment Add Attachment | Delete Attachment | View Attachment

12. Other Attachments Add Attachments | Delete Attachments | View Attachments

Project/Performance Site Location(s) Form

View Burden Statement

OMB Number: 4040-0010
Expiration Date: 10/31/2019

Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City:

County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code:

* Project/ Performance Site Congressional District:

Project/Performance Site Location 1

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City:

County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code:

* Project/ Performance Site Congressional District:

Delete Entry

Next Site

Additional Location(s)

Add Attachment

Delete Attachment

View Attachment

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

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

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

Credential, e.g., agency login:

*** Project Role:** PD/PI **Other Project Role Category:**

Degree Type:
Degree Year:

***Attach Biographical Sketch** Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

PROFILE - Senior/Key Person 1

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

Credential, e.g., agency login:

*** Project Role:** **Other Project Role Category:**

Degree Type:
Degree Year:

Attach Biographical Sketch Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

Delete Entry Next Person

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.

PHS Fellowship Supplemental Form

PHS Fellowship Supplemental Form

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Introduction

1. Introduction to Application (for Resubmission applications) — Add Attachment | Delete Attachment | View Attachment

Fellowship Applicant Section

2. * Applicant's Background 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
6. * Selection of Sponsor and Institution — Add Attachment | Delete Attachment | View Attachment
7. Progress Report Publication List (for Renewal applications) — Add Attachment | Delete Attachment | View Attachment
8. * 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

11. Description of Institutional Environment and Commitment to Training — Add Attachment | Delete Attachment | View Attachment

Other Research Training Plan Section

Vertebrate Animals

The following item is taken from the Research & Related Other Project Information form and repeated here for your reference. Any change to this item must be made on the Research & Related Other Project Information form.

Are Vertebrate Animals Used? ☐ Yes ☐ No

12. Are vertebrate animals euthanized? ☐ Yes ☐ No

If **"Yes"** to euthanasia
Is method consistent with American Veterinary Medical Association (AVMA) guidelines? ☐ Yes ☐ No

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

13. Vertebrate Animals — Add Attachment | Delete Attachment | View Attachment

PHS Fellowship Supplemental Form

Other Research Training Plan Information

14. Select Agent Research — Add Attachment | Delete Attachment | View Attachment

15. Resource Sharing Plan — Add Attachment | Delete Attachment | View Attachment

16. Authentication of Key Biological and/or Chemical Resources — Add Attachment | Delete Attachment | View Attachment

Additional Information Section

17. Human Embryonic Stem Cells

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

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

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

Cell Line(s):

X

Add

18. Alternate Phone Number:

19. Degree Sought During Proposed Award:

Degree: | If "other", indicate degree type: | Expected Completion Date (MM/YYYY): | Reset Entry

20. * Field of Training for Current Proposal:

21. * Current or Prior Kirschstein-NRSA Support? ☐ Yes ☐ No

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

* Level	* Type	Start Date *(if known)*	End Date *(if known)*	Grant Number *(if known)*	
X					Reset Entry

Add

22. * Applications for Concurrent Support ☐ Yes ☐ No

If yes, describe in an attached file: — Add Attachment | Delete Attachment | View Attachment

23. * Citizenship:

U.S.Citizen U.S. Citizen or Non-Citizen National? ☐ Yes ☐ No

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 applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here: ☐

24. ☐ Change of Sponsoring Institution — Name of Former Institution:

PHS Fellowship Supplemental Form

Budget Section

All Fellowship Applicants:

25. * Tuition and Fees: None Requested Funds Requested:

Year 1
Year 2
Year 3
Year 4
Year 5
Year 6 *(when applicable)*

Total Funds Requested:

Senior Fellowship Applicants Only:

26. Present Institutional Base Salary: Amount | Academic Period | Number of Months | Reset Entry

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

a. Federal Stipend Requested: Amount | Number of Months

b. Supplementation from Other Sources: Amount | Number of Months

Type (e.g., sabbatical leave, salary)

Source

Appendix

28. Appendix Add Attachments | Delete Attachments | View Attachments

PHS Human Subjects And Clinical Trials Information

PHS Human Subjects and Clinical Trials Information

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment | Delete Attachment | View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

x 1) Please attach Human Subject Study 1 — Add Attachment | Delete Attachment | View Attachment

Add New Study

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
x		☐	Add Attachment | Delete Attachment | View Attachment

Add New Delayed Onset Study

Check Form for Errors | Save

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No

1.3. Exemption Number ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? ☐ Yes ☐ No

1.4.b. Are the participants prospectively assigned to an intervention? ☐ Yes ☐ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ☐ Yes ☐ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

x

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits **Minimum Age** **Maximum Age**

2.4. Inclusion of Women, Minorities, and Children Add Attachment | Delete Attachment | View Attachment

2.5. Recruitment and Retention Plan Add Attachment | Delete Attachment | View Attachment

2.6. Recruitment Status

2.7. Study Timeline Add Attachment | Delete Attachment | View Attachment

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Inclusion Enrollment Report

Remove Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource ☐ Yes ☐ No

2. * Enrollment Location Type ☐ Domestic ☐ Foreign

3. Enrollment Country(ies)

Add New Country

4. Enrollment Location(s)

5. Comments

Planned

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

Cumulative (Actual)

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

< Previous Report | Report 1 of 1 | Next Report >

|<< First Report | Delete Report | Last Report >>|

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects Add Attachment Delete Attachment View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

If yes, describe the single IRB plan Add Attachment Delete Attachment View Attachment

3.3. Data and Safety Monitoring Plan Add Attachment Delete Attachment View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☐ No

3.5. Overall Structure of the Study Team Add Attachment Delete Attachment View Attachment

Section 4 - Protocol Synopsis

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

X	Intervention Type	
	Name	
	Description	

Add New Intervention

4.2.d. Study Phase

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No

4.2.e. Intervention Model

4.2.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

X	Name	
	Type	
	Time Frame	
	Brief Description	

Add New Outcome

4.4. Statistical Design and Power — Add Attachment | Delete Attachment | View Attachment

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention? Yes No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status — Add Attachment | Delete Attachment | View Attachment

4.7. Dissemination Plan — Add Attachment | Delete Attachment | View Attachment

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments — Add Attachments | Delete Attachments | View Attachments

PHS Assignment Request Form

View Burden Statement

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 3/31/2020

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

If you have a preference for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation and enter it below. All requests will be considered; however, assignment requests cannot always be honored.

Awarding Components: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

	First Choice	Second Choice	Third Choice
Assign to Awarding Component:			
Do Not Assign to Awarding Component:			

Study Section Assignment Request *(optional)*

If you have a preference for study section assignment, use the link below to identify the appropriate study section (e.g., NIH Scientific Review Group or Special Emphasis Panel) and enter it below. Remove all hyphens, parentheses, and spaces. All requests will be considered; however, assignment requests cannot always be honored.

Study Sections: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

	First Choice	Second Choice	Third Choice
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 review your application and why *(optional)* *Only 1000 characters allowed*

Identify scientific areas of expertise needed to review your application *(optional)*
Note: Please do not provide names of individuals

	1	2	3	4	5
Expertise: *Only 40 characters allowed*					