FORMS VERSION I SERIES

Released: November, 2024

MULTI - PROJECT INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) APPLICATION PACKAGES

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

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M.100 - How to Use the Application Instructions

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

View the How to Apply Video Tutorials.

Quick Links

Helpful Links

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

- NIH Grants & Funding Glossary
- Grants Policy Statement
- NIH 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 M.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 Notice of Funding Opportunity, to complete your application.

The Notice of Funding Opportunity (NOFO) will include specific instructions and the forms needed for your application submission.

> Remember that the NOFO 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 Determine the Correct Application Instructions for Your Activity Code to identify the 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 NOFO, 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 M.130 - Program Overview section for context for program specific instructions.

IMPORTANT: Do Not Include Personal Identifiable Information (PII) Or Protected Health Information (PHI) In the Application

Sensitive PII (e.g., Social Security Number, personal financial information, Alien Registration Number) and PHI (e.g., personal medical conditions) require strict handling due to the increased risk to an individual if the data is compromised. Documents containing sensitive PII or PHI must not be included in the application.

Step 5. Stay informed of policy changes and updates.

- Refer to the M.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.

Step 6. Understand what data NIH makes public.

Information submitted as part of the application will be used by reviewers to evaluate the scientific merit of the application and by NIH staff to make the grant award and monitor the grant after award. The exception to this is the M.600 - PHS Assignment Request Form, which is only seen by staff in the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR). There are also specific application attachment exceptions. The 21. Cover Letter Attachment on the SF 424 R&R Form is only seen by staff in the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR). The Other Plan(s) attachment containing the Data Management and Sharing (DMS) Plan is only seen by NIH staff and will not be used by reviewers to evaluate the scientific merit of the application unless data sharing is integral to the project design and specified in the NOFO.

If the application is funded, the following fields will be made available to the public through the NIH Research Portfolio Online Reporting Tool (RePORTER) and will become public information:

- Name of Program Director/Principal Investigator (PD/PI), to also include Project Leaders on sub-projects to multi-project projects
- PD/PI title
- PD/PI email address
- Organizational name
- Organizational address
- Project summary/abstract
- Public health relevance statement

In addition, key elements related to ongoing funded projects will be made available to the public, including those listed in the data dictionary at ExPORTER. Changes to the elements made publicly available are announced through notices in the NIH Guide for Grants and Contracts and/or updates to the NIH Grants Policy Statement.

M.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 Notice of Funding Opportunity (NOFO) for your research and learn about key information you will find in the NOFO.

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 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, use of hyperlinks and URLs, etc.

Rules for Text Fields

Learn the rules for form text fields – allowable characters, cutting and pasting, character limits, and formatting.

Page Limits

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

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, limitation on use of hyperlinks and URLs, 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 NOFO 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 recipient monitoring and reporting requirements.

Resources

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 recipients 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.

M.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 - November, 2024

How to Use the Application Instructions

- Minor text updates throughout to align with terminology in 2 CFR 200.

SF-424 Research and Related (R&R) Form Changes

Senior Key Person Profile (Expanded) Form

- Removed instructions for D. Scholastic Performance in the "Instructions for a Biographical Sketch."

Forms-I Changes

FORMS-I application packages incorporate the latest versions of the PHS forms managed by NIH (OMB Number: 0925-0001 and 0925-0770, Expiration Date: 01/31/2026). OMB approval for FORMS-I changes are underway and the updated expiration dates will be provided and incorporated once they are finalized.

PHS 398 Cover Page Supplement Form

- Updated "Change of Investigator/Change of Organization" Section label.

PHS 398 Research Training Plan Form

- Added new item 3. Recruitment Plan to Enhance Diversity in the "Training Program Plan" Section. Moved instructions for the Recruitment Plan to Enhance Diversity from the 2. Program Plan to the new item 3. Updated instructions for the 2. Program Plan throughout.
- Updated instructions for the "Program Overview" section of the 7. Progress Report (for Renewal Applications) and added instructions for Renewal Applications to the 5. Plan for Instruction in Methods for Enhancing Reproducibility.
- Renumbered form fields.

PHS Fellowship Supplemental Form

- Renamed "Candidate Section" (formerly "Fellowship Applicant Section") and item 2. Goals, Preparedness, and Potential (formerly 2. Applicant's Background and Goals for Fellowship Training). Updated instructions. Renamed "Candidate Section" (formerly "Fellowship

Applicant Section") and item 2. Goals, Preparedness, and Potential (formerly 2. Applicant's Background and Goals for Fellowship Training). Updated instructions.

- Streamlined and Consolidated items in the "Research Training Plan" Section and removed the former 5. Respective Contributions and 6. Selection of Sponsor and Organization. Relabeled items within section and updated instructions as follows:
    - Training Activities and Timeline
    - Research Training Project Specific Aims
    - Research Training Project Strategy
- Streamlined and Consolidated items in the former "Sponsor(s), Collaborator(s), and Consultant(s) Section" and "Organizational Environment and Commitment to Training Section" and combined under the "Commitment to Candidate, Mentoring, and Training Environment" Section and removed the former 9. Sponsor and Co-Sponsor Statements and 11. Description of Organizational Environment and Commitment to Training. Relabeled items within section and updated instructions as follows:
    - Sponsor(s) Commitment
    - Letters of Support from Collaborators, Contributors and Consultants
    - Description of Candidate's Contribution to Program Goals.
- Updated 26, Childcare Costs to reflect changes in amount of childcare cost support available and new eligibility for F99 awards.
- Renumbered form fields

PHS Assignment Request Form

- Reduced data entry redundancy on the form by removing the "Funding Opportunity Number" and "Funding Opportunity Title" fields.
- Reordered "List individuals who should not review your application and why" and "Identify scientific areas of expertise needed to review your application" fields.

Form Screenshots

- Updated form screenshots.

M.130 - Program Overview

Quick Links

Multi-project Applications ("M" Series).

Multi-project Applications ("M" Series)

A multi-project application is a single submission with multiple, interrelated components that share a common focus or objective.

A component is a distinct, reviewable part of a multi-project application for which there is a business need to gather detailed information as defined in a particular Notice of Funding Opportunity (NOFO). Components typically include general information (component organization, project period, project title, etc.), information about performance sites, information about proposed work to be accomplished, and a budget.

Additional Instructions for Multi-project:

Additional multi-project instructions will be denoted by a gray call-out box with red color coding and with the heading "Additional Instructions for Multi-project" throughout these application instructions.

Although multi-project applications use the same forms used for single-project applications, there are some differences in the way multi-project applications are structured. Every multi-project application includes:

- **A Single Overall Component:** The Overall Component describes the entire application and provides an overview of how each of the other components fit together.
- **One or more Other Component Types:** Other Component types (e.g., Admin Core, Project Core) will vary by opportunity and will be specified in the NOFO.
- **Summaries:** Information is automatically compiled from the data provided by the applicant in the individual components and included as part of the Overall Component in the agency-assembled application to help reviewers and staff work with the application. The following summaries are generated:
  - Component
  - Performance Sites
  - Human Subjects - Clinical Trials – Vertebrate Animals- hESC
  - Human Embryonic Stem Cell Lines
  - Budget
  - Program Income
  - Senior/Key Personnel
  - Biosketches

For information on how your application will be automatically assembled for review and funding consideration after submission, see the How eRA Assembles Multi-project Applications file.

Before Applying:

1. **Become familiar with Activity Code:** Applicants should become familiar with the activity code(s) for which support is being requested. A comprehensive list of all activity codes, with their descriptions, is available on the Activity Codes Search Results website.
2. **Refer to your specific NOFO:** Refer to your specific NOFO for specific information associated with the award mechanism, including special application instructions.
    - The NOFO will specify the types of Other Components that should be used when preparing the application, whether each component is optional or required, and any restrictions on the number of times each component can be included in an application.
3. **Contact Awarding Component:** Applicants are encouraged to consult with the NIH Scientific/Research contact of the appropriate awarding component prior to submitting an application, as eligibility criteria, support levels, and availability of awards may vary among NIH Institutes or Centers and other PHS agencies.

Collaborating with Other Organizations

Multi-project applications often include a number of collaborating organizations in addition to the applicant organization. The applicant organization always has primary responsibility for and leads the Overall Component. A collaborating organization may be responsible for a small part of a component or have lead responsibility for an entire Other Component within the application.

Depending on the role of the collaborating organization(s) in the project, there are two approaches to structuring a component:

A. Collaborating Organization as the Lead of a Component:

When the bulk of the leadership and work on a component (other than the Overall Component) is performed by a collaborating organization, then that organization can be set up as the lead organization for that component. All the component forms (including the SF 424 R&R Form and the R&R Budget Form) are completed using the collaborating organization's information. On the R&R Budget Form, use the Budget Type "Project" to identify it as the primary budget for the component and provide the collaborating organization's Unique Entity Identifier (UEI) number and name. Any other organizations involved in the component (including the applicant organization) are included in subaward/consortium budget forms.

From an administrative perspective, the entire component (minus any work done by the applicant organization) is treated as a subaward/consortium to the applicant organization. The structure of the application reflects where the proposed work is being done, not the flow of funds. eRA systems use the Unique Entity Identifier (UEI) numbers included on budget forms to determine the flow of funds.

B. Collaborating Organization as a Consortium in a Component:

When a collaborating organization does not have a leadership role for a component, then the applicant organization is the component lead, and any collaborating organizations are included using the subaward/consortium budget form.

Multi-project Application Component Forms

You must complete a set of forms for each component.

The assembled application image created for a multi-project application has a predefined order. For information on multi-project application assembly, see the How eRA Assembles Multi-project Applications file.

The chart below summarizes which forms must be completed for each component.

Component Data Forms

Form	Overall	Admin Core, Core Project, Other named components	Indiv Career Dev	Career Dev	NRSA Training
SF424 R&R cover	✓	✓	✓	✓	✓
PHS 398 Cover Page Supplement	✓	✓	✓	✓	✓
R&R Other Project Information	✓	✓	✓	✓	✓
Project/Performance Sites	✓	✓	✓	✓	✓
R&R Sr/Key Person Profile (Expanded)	✓	✓	✓	✓	✓
PHS Human Subjects and Clinical Trials Information	✓	✓	✓	✓	✓
PHS Assignment Request Form	Optional				
R&R Budget		✓	✓	✓	
R&R Subaward Budget Attachment		Optional	Optional	Optional	
PHS 398 Training Budget					✓
Training Subaward Budget Attachment Form					Optional
PHS Additional Indirect Costs	Optional				
PHS 398 Research Plan	✓	✓			
PHS 398 Career Development Award Supplemental Form			✓		

Form	Overall	Admin Core, Core Project, Other named components	Indiv Career Dev	Career Dev	NRSA Training
PHS 398 Research Training Program Plan				✓	✓

Disclosure Requirements Regarding Ties to Foreign Countries

Effective for competing applications submitted on or after September 5, 2023, applicants will be required to disclose all funded and unfunded relationships with foreign countries, using the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries form, (referred to hereafter as the SBIR STTR Foreign Disclosure Form) for all owners and covered individuals.

Upon request, applicants will submit the completed SBIR STTR Foreign Disclosure Form via the Just-In-Time (JIT) process described in the NIH GPS section 2.5.1 Just-in-Time Procedures. The SBIR STTR Foreign Disclosure Form and any additional agency-specific information must be submitted electronically using the Just-in-Time feature in the eRA Commons. Applicants must continue to comply with NIH Other Support disclosure requirements as provided in Section 2.5.1. SBC applicants applying to CDC and FDA will follow each agency's policies for submitting additional documents during the pre-award process. Applicants may be required to provide similar information on the SBIR STTR Foreign Disclosure Form that is also submitted as a part of the other support reporting for senior/key personnel identified in the application. Applicants that do not submit the completed SBIR STTR Foreign Disclosure Form during the JIT process will not be considered for funding.

Denial of Awards

Applicants are encouraged to consider whether their entity's relationships with foreign countries of concern will pose a security risk. Prior to issuing an award, NIH, CDC, and FDA will determine whether the SBC submitting the application:

- has an owner or covered individual that is party to a malign foreign talent recruitment program;
- has a business entity, parent company, or subsidiary located in the People's Republic of China or another foreign country of concern; or
- has an owner or covered individual that has a foreign affiliation with a research institution located in the People's Republic of China or another foreign country of concern.

A finding of foreign involvement with countries of concern will not necessarily disqualify an applicant. NIH, CDC, and FDA will provide SBC applicants the opportunity to address any identified security risks prior to award. Final award determinations will be based on whether the applicant's involvement falls within any of the following risk criteria, per the Act:

• interfere with the capacity for activities supported by NIH, CDC, or FDA to be carried out;

• create duplication with activities supported by NIH, CDC, or FDA;

• present concerns about conflicts of interest;

• were not appropriately disclosed to NIH, CDC, or FDA;

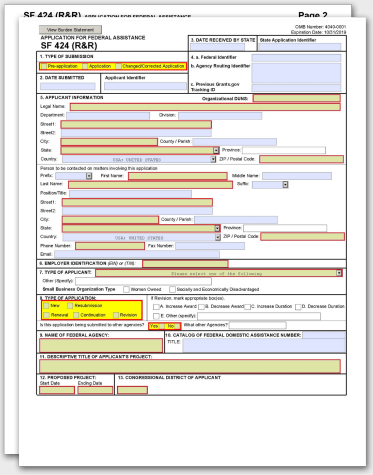
• violate Federal law or terms and conditions of NIH, CDC, or FDA; or

• pose a risk to national security.

NIH, CDC, and FDA will not issue an award under the SBIR/STTR program if the covered relationship with a foreign country of concern identified in this guidance is determined to fall under any of the criteria provided above, and the risk cannot be resolved.

M.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

Additional Instructions for Multi-project:

Overall Component: Fill in all the SF424 (R&R) Form fields, as they are all collected.

Other Components: You need to fill in only a subset of fields in the SF424 (R&R) Form. Skip the other fields, as any information provided in them will be discarded. The fields you must fill in are:

5. Applicant Information
7. Type of Applicant (Optional)
11. Descriptive Title of Applicant's Project
12. Proposed Project

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 Notice of Funding Opportunity (NOFO).

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 NOFO or notice in the NIH Guide for Grants & Contracts.

Applications in response to a NIH Notice of Special Interest require the notice number (e.g., NOT-IC-FY-XXX) to be entered into this field in order to assign and track applications and awards for the described initiative.

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.

Additional Instructions for Multi-project:

Other Components: The "Applicant Information" section is required and applies to the lead organization of the component.

Unique Entity Identifier (UEI):

This field is required.

Enter the UEI of the applicant organization.

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

If your organization does not already have a UEI, you will need to go to the System for Award Management (SAM.gov) to register and obtain a UEI.

Additional Instructions for Multi-project:

Other Components: If a component is led by an organization other than the applicant organization, then you must provide the lead organization's4UEI. If the organization does not already have a UEI, you will need to go to the System for Award Management (SAM.gov) to obtain a UEI. However, the lead organization does not need to be registered in SAM or in eRA Commons at the time of application. SAM registration is encouraged since it helps staff process your application if you are selected for funding.

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 (e.g., Payment Management System (PMS) Entity Identification Number), 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 Multi-project:

Other Components: You may fill out "7. Type of Applicant," but it is optional.

Other (Specify):

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

Women Owned:

Do not use the "Women Owned" checkbox.

Socially and Economically Disadvantaged:

Do not use the "Socially and Economically Disadvantaged" checkbox.

Note: NIH, CDC, and FDA use the Business Type information provided in the System for Award Management entity record for the applicant organization, rather than the "Woman Owned" and "Socially and Economically Disadvantaged" checkboxes, to determine the small business organization type. For more information, see the NIH Guide Notice on Small Business Organization Type Information Pulled from System for Award Management Record Rather than Grant Application Form.

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 for descriptions

- **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 NOFOs.
- **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.

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 NOFO.

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.

Note: CFDA is equivalent to the Assistance Listing Number (ALN). The application forms and instructions will be updated in the future to align with this updated terminology.

11. Descriptive Title of Applicant's Project

This field is required.

Additional Instructions for Multi-project:

Other Components: The "Descriptive Title of Applicant's Project" section 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

Additional Instructions for Multi-project:

Other Components: The "Proposed Project" section is required.

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 NOFO.

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

See M.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.

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.

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 NOFO.

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 NOFO indicates that cost sharing is a requirement.

d. Estimated Program Income

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

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 and Objectives.

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 recipient organization 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 NOFO 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 Recipient 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 NOFO, 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 NOFO, 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 recipient organization, or successor-in-interest.

Format:

Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the NOFO 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:

Do not use the cover letter to communicate application assignment preferences. The **Assignment Request Form** is provided for that purpose.

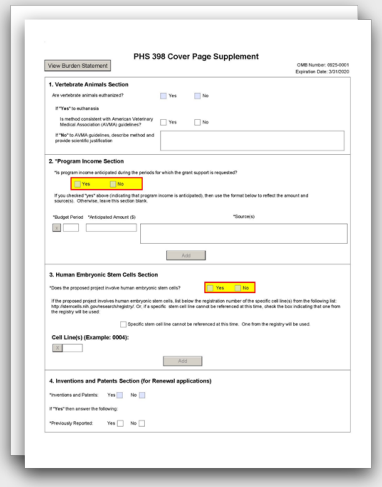
The letter should contain any of the following information, as applicable:

1. Application title.
2. Title of NOFO (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 M.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 Data Management and Sharing and Genomic Data Sharing and Section 8.2.3.2: Genomic Data Sharing (GDS) Policy).

9. Include a statement in the cover letter if the proposed studies involve human fetal tissue obtained from elective abortions (HFT), regardless of whether or not Human Subjects are involved and/or there are costs associated with the HFT. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions.

M.210 - PHS 398 Cover Page Supplement Form

The PHS 398 Cover Page Supplement Form is used for all grant applications except fellowships. This form collects information on human subjects, vertebrate animals, program income, human embryonic stem cells, inventions and patents, and changes of investigator/change of organization.



View larger image

Quick Links

1. Vertebrate Animals Section

Are vertebrate animals euthanized?

You must answer this question if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the M.220 – R&R Other Project Information Form.

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

Additional Instructions for Multi-project:

Overall Component: If vertebrate animals will be euthanized in any Component, then you must answer "Yes" to the "Are vertebrate animals euthanized?" question.

If "Yes" to euthanasia: Is method consistent with American Veterinary Medical Association (AVMA) guidelines?

You must answer this question if you answered "Yes" to the "Are vertebrate animals euthanized?" question above. Check "Yes" or "No" to indicate whether the method of euthanasia is consistent with the 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 the "Is method consistent with AVMA guidelines?" question, you must describe (in 1000 characters or fewer) the method of euthanasia and provide a scientific justification for its use. This justification will be reviewed by Office of Laboratory Animal Welfare (OLAW).

If you answered "Yes" to the "Is method consistent with AVMA guidelines" question, skip this question.

2. Program Income Section

Is program income anticipated during the periods for which the grant support is requested?

This field is required.

If program income is anticipated during the periods for which grant support is requested, check "Yes," and complete the rest of the "Program Income" section.

If no program income is anticipated, check "No" and skip the rest of the "Program Income" section.

Additional Instructions for Multi-project:

Overall Component: If you anticipate program income on any component, then answer "Yes." Skip the other fields, as any information provided in them will be discarded. Instead of program income information being provided in the Overall Component, a system-generated summary of all program income information that you provide in Other Components will be included in the summaries section of the assembled application image.

Other Component: If you anticipate program income on any component, then answer "Yes." Provide the budget period, anticipated amount, and source information.

Budget Period:

Enter the budget periods for which program income is anticipated. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.

Anticipated Amount ($):

Enter the amount of anticipated program income for each budget period listed.

Source(s):

Enter the source of anticipated program income for each budget period listed.

3. Human Embryonic Stem Cells Section

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?

This field is required.

If the proposed project involves human embryonic stem cells (hESC), check "Yes" and complete the rest of the "Human Embryonic Stem Cells" section.

- Use of the cell lines must be in accordance with the NIH Guidelines for Human Stem Cell Research.

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

Additional Instructions for Multi-project:

Overall Component: If human embryonic stem cells are used in any Component, then you must answer "Yes."

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.

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.

Additional Instructions for Multi-project:

Overall and Other Components: If you cannot choose an appropriate cell line from the registry at this time, provide a justification in the M.400 - PHS 398 Research Plan Form, Research Strategy attachment.

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.

Additional Instructions for Multi-project:

Overall Component: Skip the "Cell Line(s)" field, as any information provided here will be discarded. Instead of cell line information being provided in the Overall Component, a system-generated summary of all cell line information that you provide in Other Components will be included in the summaries section of the assembled application image.

Other Component: Provide any cell line information relevant to the work being done in that component.

For more information:

See NIH's Stem Cell Information page for additional information on stem cells, Federal policy statements, and guidelines on federally funded stem cell research.

4. Human Fetal Tissue Section

Does the proposed project involve human fetal tissue from elective abortions?

This field is required.

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), check "Yes" and complete the rest of the "Human Fetal Tissue" section.

If the proposed project does not involve the use of human fetal tissue obtained from elective abortions (HFT), check "No" and skip the rest of the "Human Fetal Tissue" section.

Additional Instructions for Multi-project:

If the answer is "yes" then provide the HFT Compliance Assurance:

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), the applicant must provide a letter, signed by the PD/PI, assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documenting that HFT was not obtained or acquired for valuable consideration. The PDF-formatted letter must be named 'HFTComplianceAssurance.pdf'.

If the answer is "yes" then provide the HFT Sample IRB Consent Form

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), provide a blank sample of the IRB-approved consent form. The PDF-formatted form must be a blank sample and named 'HFTSampleIRBConsentForm.pdf'.

o The informed consent for use of HFT from elective abortions requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, that informed consent for donation of HFT occurred after the informed consent for abortion was obtained will not affect the method of abortion, and that no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT. The form must be signed by both the woman and the person who obtains the informed consent.

For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions.

5. Inventions and Patents Section (for Renewal applications)

Who must complete the "Invention and Patents" section:

Complete the "Inventions and Patents" section only if you are submitting a renewal application or a resubmission of a renewal application.

Inventions and Patents:

If no inventions were conceived or reduced to practice during the course of work under this project, check "No" and skip the remainder of the "Inventions and Patents" section.

If any inventions were conceived or first actually reduced to practice during the previous period of support, check "Yes."

NIH recipient organizations must promptly report inventions to the Division of Extramural Inventions and Technology Resources (DEITR) Branch of the Office of Policy for Extramural Research Administration (OPERA), OER, NIH, 6705 Rockledge Drive, Bethesda, MD 20892-2750, (301) 435-1986. You must report inventions in compliance with regulations at 37 CFR 401.14, which are described at Interagency Edison (iEdison). The recipient is required to submit reports electronically using iEdison. See the NIH Grants Policy Statement, Section 8.4.1.6: Invention Reporting.

Previously Reported:

If you answered "Yes" to the "Inventions and Patents" question, indicate whether this information has been reported previously to the NIH or PHS agency or to the applicant organization official responsible for patent matters.

6. Change of Investigator / Change of Organization Section

Change of Project Director/Principal Investigator:

Check this box if your application reflects a change in project director/principal investigator (PD/PI) from that indicated on your previous application or award. Note that this box not applicable to a new application, nor is a change in PD/PI permitted for revision applications.

For a multiple PD/PI application, check this box if this application represents a change in the contact PI.

If you check the box, fill in the rest of the "Change of PD/PI" section with the information for the former PD/PI according to the instructions below.

Prefix:

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

First Name:

Enter the first (given) name of the former PD/PI.

Middle Name:

Enter the middle name of the former PD/PI.

Last Name:

Enter the last (family) name of the former PD/PI.

Suffix:

Enter or select the suffix, if applicable, for the former PD/PI.

Change of Recipient Organization:

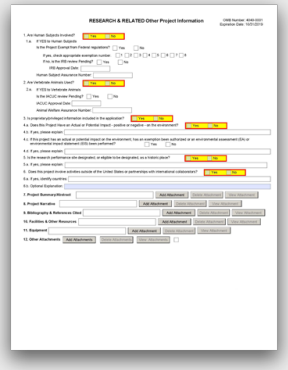
Check this box if your application reflects a change in recipient organization from that indicated on your previous application or award. This question is not applicable to new applications.

Name of Former Organization:

Enter the name of the former organization if this application reflects a change in recipient organization.

M.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?

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, or if the proposed activities include public health surveillance activities described in 45 CFR 46.102(l)(2).

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 M.500 – PHS Human Subjects and Clinical Trials Information form (see exception for Training Applications in the Training-specific instructions). Follow the M.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 "Am I Doing Human Research? decision tool" 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 M.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 Multi-project:

Overall Component: If activities involving human subjects are planned at any time during the proposed project at any performance site and/or on any Other Component, check "Yes" to the "Are Human Subjects Involved?" question and complete the remaining questions as instructed.

Other Components: Answer only the "Are Human Subjects Involved?" and "Is the Project Exempt from Federal regulations?" questions.

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 M.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.

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 for 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. See NIH Grants Policy Statement Section 4.1.15 for more information.

4. Human Fetal Tissue Section

Notes on public health surveillance activities: Projects involving public health surveillance activities described in 45 CFR 46.102(l)(2) must answer questions in Section 1.a. as if the exclusion does not apply. In rare circumstances, applicants may request NIH approval for use of the exclusion in accordance with Just-in-Time procedures.

Additional Instructions for Multi-project:

Overall Component: Check all the exemptions identified in all the Other Components.

Other Components: If the Overall Component exemption is only E4 (box 4 is checked) then no other exemption number can be set for any Other Component.

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."

Additional Instructions for Multi-project:

Other Components: Skip the "If no, is the IRB review Pending?" question.

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.

Additional Instructions for Multi-project:

Other Components: Skip the "IRB Approval Date" question.

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 M.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 Multi-project:

Other Components: Skip the "Human Subject Assurance Number" field.

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 Multi-project:

Overall Component: If activities involving vertebrate animals are planned at any time during the proposed project at any performance site and/or on any Other Component, check "Yes" and complete the remaining questions as instructed.

Other Components: Answer only the "Are Vertebrate Animals Used?" question. Skip the questions in 2.a.

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."

Additional Instructions for Multi-project:

Overall Component: Complete the "Is the IACUC review Pending?" question when the answer is "Yes" to "Are Vertebrate Animals Used?"

Other Components: Skip the "Is the IACUC review Pending?" question.

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.

Additional Instructions for Multi-project:

Other Components: Skip the "IACUC Approval Date" question.

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.

Additional Instructions for Multi-project:

Other Components: Skip the "Animal Welfare Assurance Number" question.

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 recipient organization 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 NOFO 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 organization 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 Multi-project:

Overall Component: If the answer to Question 6 is "Yes" for any Other Component, then you must answer "Yes" for the Overall Component.

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 that exceeds the 30-line limit will be flagged as an error by the Agency upon submission. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity.

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 Multi-project:

Overall and Other Components: A project summary is required for both the Overall Component and all Other Components. Each project summary 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. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity. If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.

Additional Instructions for Multi-project:

Overall Component: The "Project Narrative" attachment is required.

Other Components: Refer to the specific NOFO to determine whether the "Project Narrative" attachment is required for any Other Components. **Note:** The form may

show '*' indicating it is a required field, but it is only required for the Overall Component and the '*' can be ignored for Other Components.

9. Bibliography & References Cited

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

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

Format:

Attach this information as a PDF file. See the Format Attachments page. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity.

Content:

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

Additional Instructions for Multi-project:

Overall and Other Components: The "Bibliography & References Cited" attachment should include any references cited in M.400 - PHS 398 Research Plan Form and in the M.500 - PHS Human Subjects and Clinical Trials Information 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. Active hyperlinks in this section are not allowed. 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 Interim Research Prpduct FAQ for more information.

Additional Instructions for Multi-project:

Overall and Other Components: Unless specific instructions are provided in the NOFO, applicants have the option of including the "Bibliography & References Cited" attachment in the Overall Component, Other Components, or both. User-defined bookmarks provided in the Bibliography & References Cited attachment will be included with the bookmarks of the assembled application image in eRA Commons. If you include the "Bibliography & References Cited" attachment only in the Overall Component, you may want to use bookmarks to organize references by component.

10. Facilities & Other Resources

Format:

The "Facilities & Other Resources" attachment is required unless otherwise specified in the NOFO. Use of URLs and hyperlinks in this section is not allowed unless specified in the Notice of Funding Opportunity.

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 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.

When working with biohazards and any other potentially dangerous substances, describe any special facilities and measures implemented to mitigate threats to human health and the environment. **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 Early Stage Investigator (ESI) 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 Multi-project:

Unless specific instructions are provided in the NOFO, applicants have the option of including the "Facilities & Other Resources" attachment in the Overall Component, Other Components, or both.

11. Equipment

The "Equipment" attachment is required.

Format:

Attach this information as a PDF file. Use of URLs and hyperlinks in this section is not allowed unless specified by the Notice of Funding Opportunity.

Content:

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

Additional Instructions for Multi-project:

Unless specific instructions are provided in the NOFO, applicants have the option of including the "Equipment" attachment in the Overall Component, Other Components, or both (whichever is most appropriate for your application). User-defined bookmarks provided in the Equipment attachment will be included with the bookmarks of the assembled application image in eRA Commons. If you include the "Equipment" attachment only in the Overall Component, you may want to use bookmarks to organize equipment by component.

12. Other Attachments

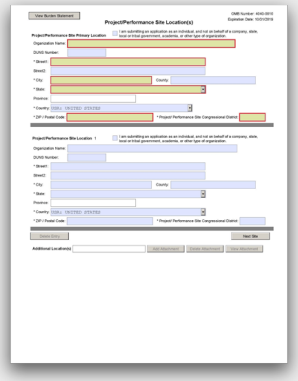
Attach a file to provide additional information only in accordance with the NOFO and/or agency-specific instructions.

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

M.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 M.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 Multi-project:

Overall Component: Include only the primary site for the entire application, which is typically the applicant organization.

Other Components: List the primary site for the component, which is typically the lead organization of the component. Describe any consortium/contractual arrangements in the "Consortium/Contractual Arrangements" attachment in M.400 – PHS 398 Research Plan Form.

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

Do not check the box for "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" unless otherwise specified by the NOFO.

Organization Name:

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

Unique Entity Identifier (UEI):

This field is required for the primary performance site.

Enter the UEI 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.

Additional Instructions for Multi-project:

Other Components: List all performance sites that apply to the specific component.

Organization Name:

Enter the organization name of the performance site location.

Unique Entity Identifier (UEI):

Enter the UEI 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)

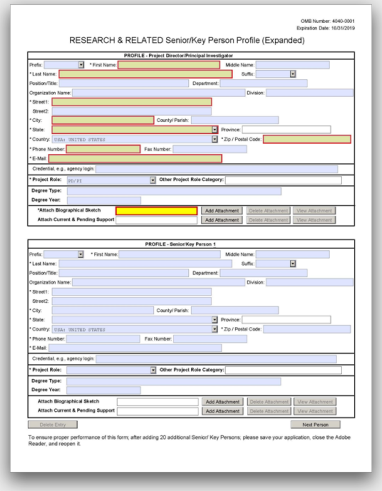
If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the "Additional Locations" section.

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

M.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 M.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

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 NOFO, 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 Multi-project:

Overall Component: List the PD/PI (or Contact PD/PI if submitting a multi-PD/PI application) for the entire application.

Other Components: List the component lead.

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.

Additional Instructions for Multi-project:

Other Components: For the "Profile – Project Director/Principal Investigator" section, enter "Other (Specify)" and enter "Project Lead" for the "Other Project Role Category" field, unless otherwise specified in the NOFO. The PD/PI role is used only in the Overall Component.

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 NOFO.

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). Hyperlinks and URLs are only allowed when specifically noted in the funding opportunity and form field instructions.

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, including ongoing and completed research projects from the past three years that you want to draw attention to (previously captured under Section D. Research Support).

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. Use of hyperlinks and URLs to cite these items is not allowed.

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Interim Research Product FAQs 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 (e.g., R36) 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 NOFO.
- 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, Scientific Appointments and Honors

List in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). 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.
- Figures, tables, or graphics are not allowed.

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. Use of hyperlinks and URLs to cite these items is not allowed.

You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Interim Research Product FAQs for more information.

You may provide a hyperlinked URL to a full list of your published work. This hyperlinked 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. Scholastic Performance

No longer required for NIH applications. Enter "N/A" or leave blank. See NOT-OD-24-107 and Changes to Fellowship Applications.

Additional Instructions for Multi-project:

Each Senior/Key Person, including the PD/PI, is allowed one biosketch for the entire application. If an individual will participate on multiple components, attach the biosketch to any single component.

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.

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:

This field is required. Applies to Senior/Key Personnel as defined in the NIH Grants Policy Statement (NIH GPS 1.2) as well as Other Significant Contributors (OSCs). Enter the assigned eRA Commons username for the senior / key Person.

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.

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 NOFO.

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)

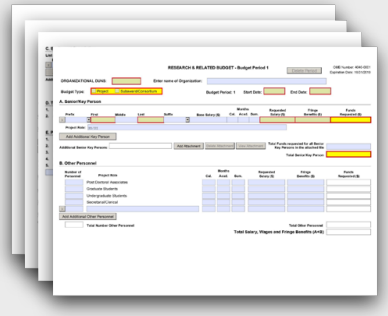
If you need to add more Senior/Key Person Profiles than the form allows, enter the information in a separate file and attach it as a PDF.

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

M.300 - R&R Budget Form

The R&R Budget Form is used in the majority of applications; however, it is important to refer to your specific NOFO for guidance on which budget form(s) are allowed for your application.

Some application forms packages include two optional budget forms — (1) the R&R Budget Form and, (2) PHS 398 Modular Budget Form. Include only one of these forms, but not both, in your application.



View larger image

Quick Links

Who should use the R&R Budget Form?

There are two primary types of Budget Forms: detailed R&R and PHS 398 modular. Generally, you must use the R&R Budget Form if you are applying for more than $250,000 per budget period in direct costs, and you must use the Modular Budget Form if you are applying for less than $250,000. However, some grant mechanisms or programs (e.g., training grants) may require other budget forms to be used. Refer to your NOFO and to the following instructions for guidance on which Budget Form to use.

Note: The terms "detailed budget" and "R&R Budget" are used interchangeably.

If you are requesting a budget with $500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting the

application. For more information on applications that request $500,000 or more in direct costs, see the NIH Grants Policy Statement, Section 2.3.7.2: Acceptance for Review of Unsolicited Applications Requesting $500,000 or More in Direct Costs.

Special Instructions for Foreign Organizations (Non-domestic [non-U.S.] Entities): All competing (new, renewal, resubmission, and revision) grant applications from foreign (non-U.S.) organizations must use the R&R Budget Form. Do not use the PHS 398 Modular Budget Form. For additional information, see NIH Guide Notice on the Requirement for Detailed Budget Submissions from Foreign Institutions and the NIH Grants Policy Statement, Section 13.3.1: Budget. Applications from foreign organizations must request budgets in U.S. dollars.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application, you must use the R&R Budget Form and cannot use the PHS Modular Budget Form, regardless of the activity code. Whether or not you incur costs to obtain HFT, you will need to include a "Human Fetal Tissues Costs" line item (F.8-17) and a Budget Justification attachment (L).

Note on Subawards/Consortiums: If you have a subaward/consortium, you must use the R&R Subaward Budget Attachment(s) Form in conjunction with the R&R Budget Form. The prime must extract the R&R Subaward Budget Attachment(s) from the R&R Subaward Budget Attachment(s) Form and send the extracted file to the subaward/consortium. The consortium should complete the R&R Subaward Budget Attachment, following the instructions here and in M.310 – R&R Subaward Budget Attachment(s) Form.

For more information:

For more information on how to prepare your budget, see NIH's Develop Your Budget page.

Additional Instructions for Multi-project:

Developing a Multi-project Budget: The structure of a Multi-project application reflects where the work will be done and not necessarily the flow of funds. If most of the work for a particular component is done by a collaborating organization, then that organization can be set up as the lead organization for that component.

The main budget form for the component must reflect the Unique Entity Identifier (UEI) for the lead organization and Project for the Budget Type. If the applicant organization is responsible for a portion of the work for that component, then their costs would be reflected on a Subaward Budget Form with the applicant organization UEI and Subaward / Consortium for the Budget Type. Subaward Budget Forms simply record budget data. They do not indicate that funds must flow through the lead organization for the component.

The UEI on each budget form is used to identify the budget data associated with each organization. When the UEI on the budget form is the same as the UEI on the Overall Component's SF424 R&R form, the budget data is associated with the applicant organization. When the UEI is different, it is seen as belonging to a subaward.

For more information, refer to NIH's Frequently Asked Questions on Applying Electronically.

Overall Component: Most budget data is collected within the Other Components. Complete only the M.200 - SF 424 (R&R) Form, Estimated Project Funding section and the M.350 - PHS Additional Indirect Costs Form (if applicable). The PHS Additional Indirect Costs Form is used to gather any additional information allowable under the recipient's negotiated F&A rate agreement needed to calculate the F&A rate for the Overall Component's first $25,000 on each subaward that leads an entire component. The PHS Additional Indirect Costs Form should not be used when all components are led by the applicant organization.

System-generated budget summaries (including a Composite Application Budget Summary) based on budget data collected within the Other Components are included in the summaries section of the assembled application image.

Budget summaries will:

- appear in the Overall section of the assembled application image in eRA Commons;
- will be compiled from R&R budget data collected in the Other Components; and
- will be generated upon submission.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue:

- If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application, you must provide HFT budget information in the component(s) where the research involving HFT is conducted.

Special Instructions for Applications Submitted with a Data Management and Sharing Plan:

Overall Component: The "Data Management and Sharing Plan" attachment must be provided within the PHS 398 Research Plan Form in the Overall Component. Do not include budget information for Data Management and Sharing Costs in the Overall Component.

Other Components: Include budget information for Data Management and Sharing Costs within the applicable component(s). Do not include a "Data Management and Sharing Plan" attachment within the components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment provided within the PHS 398 Research Plan Form in the Overall Component.

Using the R&R Budget Form:

The location of the R&R Budget Form may vary with the type of submission (e.g., under an "Optional Forms" tab).

You must complete a separate detailed budget for each budget period requested. The form will generate a cumulative budget for the total project period. If no funds are requested for a required field, enter "0."

You must round to the nearest whole dollar amount in all dollar fields.

Competing Revision Applications: For a supplemental/revision application, complete fields for which additional funds are requested in addition to all required fields. If the initial budget period of the

supplemental/revision application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

Introductory Fields

Unique Entity Identifier (UEI):

This field is required. This field may be pre-populated and should reflect the UEI of the applicant organization (or of the lead organization for the component of a multi-project application).

Enter name of Organization:

This field may be pre-populated. Enter the name of the organization.

Budget Type:

This field is required. Check the appropriate box for your budget type, following these guidelines:

- **Project:** The budget being requested is for the primary applicant organization.
- **Subaward/Consortium:** The budget being requested is for subaward/consortium organization(s). Note, separate budgets are required only for subaward/consortium organizations that perform a substantive portion of the project. For subawards/consortiums that do not perform a substantive portion of the project, then you must include their costs in Field F5. Subawards/Consortium/Contractual Costs and in the prime's Section L. Budget Justification.

If you are preparing an application that includes a subaward/consortium that performs a substantive portion of the project, in addition to completing this form, see also the instructions for M.310 - R&R Subaward Budget Attachment(s) Form.

Additional Instructions for Multi-project:

Project: The budget being requested is for the organization leading the component.

Subaward/Consortium: The budget being requested is for other organizations performing work for the component. When the applicant organization is participating on a component, but not leading that component, their costs should be reflected on a Subaward/Consortium budget. This is true even if the money will not flow through the lead organization. The budget justification can be used to clarify the flow of funds.

Budget Period:

This field is required.

Identify the specific budget period (for example, 1, 2, 3, 4, 5).

Start Date:

This field is required and may be pre-populated from the SF 424 R&R Form. Enter the requested/proposed start date of the budget period. For period 1, the start date is typically the same date as the Proposed Project Start Date on the M.200 - SF 424 (R&R) Form.

End Date:

This field is required. Enter the requested/proposed end date of the budget period.

A. Senior/Key Person

Who to include in A. Senior / Key Person:

Include the names of senior / key persons at the applicant organization, (or organization leading the component of a multi-project application), who are involved on the project in a particular budget period. Include all collaborating investigators and other individuals who meet the senior/key person definition if they are from the applicant organization.

Consultants designated as senior/key persons in the Senior/Key Person Profile Form can be included in the "A. Senior/Key Person" section only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in Consultant Services in Question F of this form.

Who *not* to include in A. Senior / Key Person:

Do not list details of collaborators at other organizations here, as they will be provided in the Subaward Budget for each subaward/consortium organization.

Personnel listed as other significant contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section (sections "A. Senior/Key Person" and "B. Other Personnel") since no associated salary and/or fringe benefits can be requested for their contribution.

Prefix:

Enter the prefix (e.g., Mr., Mrs., Rev.), 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 the suffix (e.g., Jr., Sr., PhD), if applicable, of the senior/key person.

Base Salary ($):

Enter the annual compensation paid by the employer for the senior/key person. This includes all activities such as research, teaching, patient care, and other. An applicant organization may choose to leave this blank; however, NIH or other PHS Agency staff will request this information prior to award.

Months (Cal./Acad./Sum.):

NIH and other PHS agencies use the concept of “person months” as a metric for determining percent of effort. For more information about calculating person months, see NIH's information at Frequently Asked Questions on Person Months.

Identify the number of months the senior/key person will devote to the project in the applicable box (i.e., calendar, academic, summer).

Use either calendar months OR a combination of academic and summer months. Measurable effort is required for every senior/key person entry.

For an explanation of "measurable effort," see the Frequently Asked Questions on Senior/Key Personnel.

If effort does not change throughout the year, it is OK to use only the calendar months column.

However, you may use both the academic and summer months columns if your institutional business process requires noting each separately even if effort remains constant. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns.

If your organization does not use a 9-month academic year or a 3-month summer period, indicate your organization's definition of these in Section L. Budget Justification.

Requested Salary ($):

This field is required. Regardless of the number of months being devoted to the project, indicate the salary being requested for this budget period for the senior/key person.

Salary limitations. Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award; therefore, requested salary should be based on institutional base salary at the time the application is submitted and not adjusted for any limitation. For guidance on current salary limitations, see the NIH's Salary Cap Summary or contact your office of sponsored programs.

Graduate student compensation: NIH grants also limit compensation for graduate students. Compensation includes salary or wages, fringe benefits, and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see the NIH Grants Policy Statement, Section 2.3.7.9: Graduate Student Compensation.

Fringe Benefits ($):

Enter the amount of requested fringe benefits, if applicable, for the senior/key person.

Funds Requested ($):

This field is automatically calculated and will reflect the total requested salary and fringe benefits for the senior/key person.

Project Role:

This field is required. Identify the project role of each senior/key person. Roles should correspond to the roles included on the M.240 - R&R Senior/Key Person Profile (Expanded) Form. Note that there must be at least one PD/PI per budget period.

Additional Senior/Key Persons:

If you are requesting funds for more senior/key persons than the form allows, you must include an attachment listing the additional senior/key person(s) in this "Additional Senior/Key Persons" field. Use the same format as the budget form and include all the information identified in this section.

Total Funds requested for all persons in the attached file:

If you have attached a file with additional senior/key persons, enter the total funds requested for everyone listed in the attachment in the "Total Funds requested for all Senior/Key Persons in the attached file" field.

Total Senior/Key Persons:

This total will be automatically calculated based on the sum of the "Funds Requested" column and the "Total Funds requested for all Senior/Key Persons in the attached file" field.

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

B. Other Personnel

Number of Personnel:

For each project role category, identify the number of personnel proposed.

Administrative, Secretarial, and Clerical Support Salaries: In most circumstances, the salaries of administrative, secretarial, or clerical staff at educational institutions and nonprofit organizations are included as part of indirect costs (Section H. Indirect Costs). However, examples of situations where direct charging of administrative or clerical staff salaries may be appropriate may be found at: 45 CFR 75.403.

Inclusion of such costs may be appropriate only if all of the following conditions are met:

1. Administrative or clerical services are integral to a project or activity;
2. Individuals involved can be specifically identified with the project or activity;
3. Such costs are explicitly included in the budget or have prior written approval of the federal awarding agency; and
4. The costs are not also recovered as indirect costs.

Requests for direct charging for secretarial/clerical personnel (i.e., administrative and clerical staff) must be appropriately justified in Section L. Budget Justification. For all individuals classified as administrative/secretarial/clerical, provide a justification (in the Budget Justification) documenting how they meet all four conditions. NIH ICs may request additional information for these positions in order to assess allowability.

Postdoctoral and Graduate Students: For all postdoctoral associates and graduate students not already named in "Section A. Senior/Key Person," individually list names, roles (e.g., postdoctoral associates or graduate student), associated months, and requested salary and fringe benefits in Section L. Budget Justification.

Project Role:

List any additional project role(s) (e.g., engineer, IT professionals, etc.) in the blank(s) provided. Identify the number of each personnel proposed.

You may have up to six named roles. If you have more than six, you must combine project roles here and add an explanation about the named roles in Section L. Budget Justification.

Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.

Months (Cal./Acad./Sum.):

NIH and other PHS agencies use the concept of "person months" as a metric for determining percent of effort. For more information about calculating person months, see: NIH's Frequently Asked Questions on Person Months.

Identify the number of months devoted to the project in the applicable box (i.e., calendar, academic, summer) for each project role category.

Use either calendar months OR a combination of academic and summer months.

If effort does not change throughout the year, it is OK to use only the calendar months column.

However, you may use both academic and summer months columns if your institutional business process requires noting each separately, even if effort remains constant. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns.

If your organization does not use a 9-month academic year or a 3-month summer period, indicate your organization's definition of these in Section L. Budget Justification.

Requested Salary ($):

Regardless of the number of months being devoted to the project, indicate only the amount of salary/wages being requested for this budget period for each project role. The amount entered should reflect the total amount of funds requested for all personnel within a project role.

Salary limitations: Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award; therefore, requested salary should be based on institutional base salary at the time the application is submitted and not adjusted for any limitation. For guidance on current salary limitations, see the NIH's Salary Cap Summary or contact your office of sponsored programs.

Graduate student compensation: NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits, and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see the NIH Grants Policy Statement, Section 2.3.7.9: Graduate Student Compensation.

Fringe Benefits ($):

Enter the amount of requested fringe benefits, if applicable, for this project role category. The amount entered should reflect the total amount of fringe benefits requested for all personnel within a project role.

Funds Requested ($):

This field will be automatically calculated and will reflect the total requested salary and fringe benefits for each project role category.

Total Number of Other Personnel:

This total will be automatically calculated based on the Number of Personnel for each project role category.

Total Other Personnel:

This total will be automatically calculated based on the sum of the Funds Requested for all Other Personnel.

Total Salary, Wages and Fringe Benefits (A+B):

This total will be automatically calculated and represents the total Funds Requested for all Senior/Key persons and all Other Personnel

Special Instructions for Applications Submitted with a Data Management and Sharing Plan:

For applications submitted for due dates on or before October 4, 2023, if a Data Management and Sharing Plan is required in the proposed application, personnel costs specific to Data Management and Sharing activities must not be included here but listed as a specific line item under Section F.8.-17 Other.

For applications submitted for due dates on or after October 5, 2023, DMS costs must be requested in the appropriate costs category.

C. Equipment Description

The "C. Equipment Description" section is for you to list items and dollar amount for each item exceeding $5,000 (unless the organization has established lower levels).

Equipment Item:

Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year.

List each item of equipment separately and justify each in Section L. Budget Justification. Allowable items ordinarily will be limited to research equipment not already available for the conduct of the work.

Additional Instructions for Multi-project:

Other Components: You are allowed to add up to 100 equipment items in this list. For additional equipment items, you must list them in the "Additional Equipment" attachment.

Funds Requested:

This information is required. List the estimated cost of each item, including shipping and any maintenance costs and agreements.

Additional Equipment:

If you're requesting funds for more equipment than the form allows, you must include an attachment listing the additional equipment items in this "Additional Equipment" field. Enter the information in a separate file and attach it as a PDF. List each additional item and the funds requested for each individual item. The dollar amount for each item should exceed $5,000 (unless the organization has established lower levels).

Total funds requested for all equipment listed in the attached file:

If you have attached a file with additional equipment, enter the total funds requested for all the equipment listed in the attachment.

Total Equipment:

This total will be automatically calculated based on the sum of the "Funds Requested" column and the "Total funds requested for all equipment listed in the attached file" field.

D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions):

Enter the total funds requested for domestic travel. Domestic travel includes destinations in the U.S., Canada, Mexico, and U.S. possessions. In Section L. Budget Justification, include the purpose, destination, dates of travel (if known), and the number of individuals for each trip. If the dates of travel are not known, specify the estimated length of trip (e.g., 3 days).

2. Foreign Travel Costs:

Identify the total funds requested for foreign travel. Foreign travel includes any destination outside of the U.S., Canada, Mexico, or U.S. possessions. In Section L. Budget Justification, include the purpose, destination, dates of travel (if known), and the number of individuals for each trip. If the dates of travel are not known, specify the estimated length of trip (e.g., 3 days).

Total Travel Cost:

This total will be automatically calculated based on the sum of the Domestic and Foreign Funds Requested fields.

E. Participant/Trainee Support Costs

Unless specifically stated otherwise in a NOFO, NIH and other PHS agencies applicants should skip Section E. Participant/Trainee Support Costs. **Note:** Tuition remission for graduate students should be included in Section F. Other Direct Costs when applicable.

1. Tuition/Fees/Health Insurance:

List the total funds requested for Participant/Trainee Tuition/Fees/Health Insurance.

2. Stipends:

List the total funds requested for Participant/Trainee stipends.

3. Travel:

List the total funds requested for Participant/Trainee travel.

4. Subsistence:

List the total funds requested for Participant/Trainee subsistence.

5. Other:

Describe any other Participant/Trainee support costs and list the total funds requested for all other Participant/Trainee costs described.

Number of Participants/Trainees:

List the total number of proposed Participants/Trainees. Value cannot be greater than 999.

Total Participant/Trainee Support Costs:

This field is required if any data has been entered in "Section E. Participant/Trainee Support Costs." This total will be automatically calculated based on the sum of the Funds Requested column in

"Section E. Participant/Trainee Support Costs."

F. Other Direct Costs

1. Materials and Supplies:

List the total funds requested for materials and supplies. In Section L. Budget Justification, indicate general categories such as glassware, chemicals, animal costs, etc., including an amount for each category. Categories with amounts less than $1,000 are not required to be itemized.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue: If costs for human fetal tissue obtained from elective abortions (HFT) as defined in the NIH Grants Policy Statement are included in the proposed budget, they must **not** be included here but listed as a specific line item under *Section F.8-17 Other*.

2. Publication Costs:

List the total funds requested for publication costs. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others, the findings and products of the work conducted under the award. Include supporting information in Section L. Budget Justification.

3. Consultant Services:

List the total funds requested for all consultant services. Identify the following items in Section L. Budget Justification, as applicable:

- each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs;
- the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements;
- consulting physicians in connection with patient care; and
- persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed.

4. Automatic Data Processing (ADP)/Computer Services:

List the total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical, and education information may be requested. In Section L. Budget Justification, include the established computer service rates at the proposing organization, if applicable.

5. Subawards/Consortium/Contractual Costs:

List the total funds requested for:

1. all subaward/consortium organization(s) proposed for the project and
2. any other contractual costs proposed for the project.

This line item should include both direct and indirect costs for all subaward/consortium organizations.

Contractual costs for support services, such as laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown

of costs. When this is the case, provide detailed information as part of Section L. Budget Justification.

NIH policy provides for exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. However, you must include the full cost of consortium/subawards in this field. See the NIH Grants Policy Statement, Section 2.3.7.1: Applications that Include Consortium/Contractual F&A Costs for policy related to the exclusion of consortium/subaward amounts in determining whether an applicant is in compliance with a direct cost limitation.

6. Equipment or Facility Rental/User Fees:

List the total funds requested for equipment or facility rental/user fees. In Section L. Budget Justification, identify and justify each rental user fee.

7. Alterations and Renovations:

List the total funds requested for alterations and renovations (A&R). In Section L. Budget Justification, itemize by category and justify the costs of alterations and renovations, including repairs, painting, and removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.

Under certain circumstances the public policy requirements that apply to construction activities may also apply to A&R activities. Refer to the NIH Grants Policy Statement, Section 10.10: Construction Grants – Public Policy Requirements and Objectives for more information.

> **Special Instructions for Foreign Organizations (Non-domestic [non-U.S.] Entities):** Minor A&R costs (≤$500,000) are allowable on applications from foreign organizations and domestic organizations with foreign components. When requesting minor A&R costs under this policy, please provide detailed information on the planned A&R in the budget justification.

8-17 Other:

Add descriptions for any "other" direct costs not requested above. Use Section L. Budget Justification to further itemize and justify.

List funds requested for each of the items in lines "8-17 Other." Use lines 8-17 for costs such as patient care costs, tuition remission and SBIR/STTR "Technical Assistance" (TABA) costs. If requesting patient care costs, request inpatient and outpatient costs separately.

Lines "8-17 Other" may also be used to request direct costs related to the use of single Institutional Review Board (sIRB) for multi-site human subjects research.

For more information on charging direct and indirect costs for single IRB activities, see the Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-Site Research.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application, regardless of whether costs will be incurred, it must be noted as a single line item here. The line item must be titled "Human Fetal Tissue Costs" (without quotation marks, but following exact phrase and spacing). The line item must only be used for HFT costs and cannot include or be combined with any "Other" costs. If no cost will be incurred (e.g. if HFT will be donated), enter "0" in the "Funds Requested" column. Details regarding HFT must be specified in the Budget Justification attachment (L), pursuant to the instructions.

Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Human Fetal Tissue from Elective Abortions.

Special Instructions for Applications Submitted with a Data Management and Sharing (DMS) Plan:

For applications submitted on or before October 4, 2023, NIH recognizes that making data accessible and reusable for other researchers may incur costs. If a Data Management and Sharing Plan is required in the proposed application (see instructions for the "Other Plan(s)" attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), costs to support these activities, including personnel costs (e.g., personnel who will be curating data for the project) must be noted as a single line item. The line item must be titled "Data Management and Sharing Costs" (without quotation marks, but following exact phrase and spacing). The line item must only be used for Data Management and Sharing costs and cannot include or be combined with any "Other" costs. If no cost will be incurred, enter "0" in the "Funds Requested" column. Details regarding Data Management and Sharing costs must be specified in the Budget Justification attachment (L), pursuant to the instructions.

For applications submitted for due dates on or after October 5, 2023, NIH recognizes that making data accessible and reusable for other researchers may incur costs. If a Data Management and Sharing Plan is required in the proposed application (see instructions for the "Other Plan(s)" attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), costs to support these activities, may be requested in the appropriate cost category. Details regarding Data Management and Sharing costs must be specified in the Budget Justification attachment (L), pursuant to the instructions.

Allowable and Unallowable Costs: Allowable costs submitted in budget requests must be incurred during the performance period, even for scientific data and metadata preserved and shared beyond the award period. Budget requests must NOT include: Infrastructure costs that are included in institutional overhead (for instance, NIH Grants Policy Statement Section 7.3 Facilities and Administrative costs); costs associated with the routine conduct of research, including costs associated with collecting or gaining access to research data; or costs that are double charged or inconsistently charged as both direct and indirect costs. For more information, see Budgeting for Data Management & Sharing on the NIH Scientific Data Sharing website and additional details to help Develop Your Budget.

Additional Instructions for Multi-project:

Other Components, Special Instructions for Patient Care Costs: If inpatient and/or outpatient costs are requested, provide the names of any hospitals and/or clinics and the amounts requested for each in the Budget Justification.

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

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If

patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of Other Support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of the Clinical and Translational Science Awards (CTSA) program.

Special Instructions for Applications Submitted with a Data Management and Sharing (DMS) Plan

Other Components: Include budget information for Data Management and Sharing Costs within the applicable component(s). Do not include a "Data Management and Sharing Plan" attachment within the components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment provided within the PHS 398 Research Plan Form in the Overall Component.

Total Other Direct Costs:

This total will be automatically calculated based on the sum of the Funds Requested column in "Section F. Other Direct Cost."

G. Direct Costs

This total will be automatically calculated based on the sum of the Total funds requested for all direct costs (sections A-F).

H. Indirect Costs

Indirect costs (Facilities & Administrative [F&A] costs) are defined as costs that are incurred by a recipient for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. See the NIH Glossary's definition of Indirect Costs.

For more information:

You are encouraged to visit the following Division of Financial Advisory Services (DFAS) Websites or call DFAS staff at 301-496-2444 for guidance: Main DFAS website, DFAS Frequently Asked Questions. The following website has a listing of unallowable and unallocable costs and the related Federal Acquisition Regulation (FAR) citation for each: NIH Office of Management's Unallowable / Unallocable Costs.

Refer to the NIH Grants Policy Statement, Section 7.4: Reimbursement of Facilities and Administrative Costs for more information.

Special Instructions for Foreign Organizations (Non-domestic [non-U.S.] Entities): Foreign organizations and international organizations may request funds for limited F&A costs (8% of modified total direct costs less equipment) to support the costs of compliance with HHS and NIH requirements including, but not limited to, those related to the protection of human subjects, animal welfare, invention reporting, financial conflict of interest, and research misconduct. Foreign organizations may not include any charge-back of customs and import fees, such as consular fees, customs surtax, value-added taxes (VAT), and other related charges.

Indirect Cost Type:

Enter the type of indirect cost (e.g., Salary & Wages, Modified Total Direct Costs, etc.) and whether the cost is off-site. If more than one rate or base is involved for a given type of indirect cost, then list them as separate entries. If you do not have a current indirect (F&A) rate(s) approved by a federal agency, indicate "None--will negotiate" and include information for a proposed rate. Use Section L. Budget Justification if additional space is needed.

Indirect Cost Rate (%):

Enter the most recent indirect cost rate(s) established with the cognizant federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/oversight agency and are selected for an award, you must submit your indirect rate proposal to the NIH awarding IC or to the PHS awarding office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency. This field should be entered using a rate such as "55.5."

Indirect Cost Base ($):

Enter the amount of the base for each indirect cost type.

Funds Requested ($):

Enter the funds requested for each indirect cost type.

Total Indirect Costs:

This total will be automatically calculated from the "Funds Requested" column in "Section H. Indirect Cost."

Cognizant Federal Agency:

Enter the name of the cognizant Federal Agency and the name and phone number of the individual responsible for negotiating your rate (your point of contact). If no cognizant agency is known, enter "None."

I. Total Direct and Indirect Costs

This total will be automatically populated from the sum of Total Direct Costs (from Section G. Direct Cost) and the Total Indirect Costs (from Section H. Indirect Costs).

J. Fee

Do not include a fee in your budget, unless the NOFO specifically allows inclusion of a "fee." If a fee is allowable, enter the requested fee.

K. Total Costs and Fee

This total will be automatically calculated from the sum of Total Direct Costs and Fee (from sections "I. Total Direct and Indirect Costs" and "J. Fee").

L. Budget Justification

The "Budget Justification" attachment is required. Attach only one file.

Use the Budget Justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. If you have a quote(s), you may include it here (information in the quote may be not used to supplement information provided in page-limited sections of the application, such as the Research Strategy). The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support, and other direct cost categories.

In addition to the justifications described in the above sections, also include a justification for any significant increases or decreases from the initial budget period. Justify budgets with more than a standard escalation from the initial to the future year(s) of support.

Also use the Budget Justification to explain any exclusions applied to the F&A base calculation.

If your application includes a subaward/consortium budget, a separate Budget Justification must be submitted. See M.310 - R&R Subaward Budget Attachment(s) Form.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application include a detailed justification including the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. This information must be included if costs for the HFT are assigned to the grant or if the HFT is acquired under the grant at no costs. The HFT justification must be clearly labeled in the budget justification attachment.

Special Instructions for Applications Submitted with a Data Management and Sharing (DMS) Plan:

If a Data Management and Sharing Plan is required in the proposed application (see instructions for the "Other Plan(s)" attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), include a brief justification of the proposed activities that will incur costs. The Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" within the budget justification attachment followed by the estimated dollar amount (total direct costs). Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be no more than half a page. For more information, see Budgeting for Data Management & Sharing on the NIH Scientific Data Sharing website and additional details to help Develop Your Budget.

Research & Related Budget - Cumulative Budget

All values on this form are automatically calculated, and the fields are pre-populated. They present the summations of the amounts you entered previously, under Sections A through K, for each of the individual budget periods. Therefore, no data entry is allowed or required to complete this "Cumulative Budget" section.

If any of the amounts displayed on this form appear to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such corrections, you will need to revisit the appropriate budget period form(s).

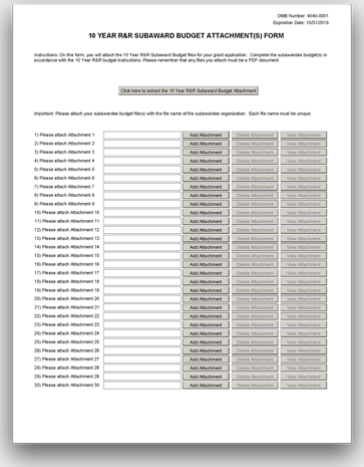
M.310 - R&R Subaward Budget Attachment(s) Form

The R&R Subaward Budget Attachment(s) Form is used for applications with a subaward or consortium.

This form is required only when the prime recipient is submitting an R&R Budget Form and has subaward/consortium budgets.

Applicants using the Modular Budget Form should see M.320 - Modular Budget Form for instructions concerning information on consortium budgets.

View larger image


10 YEAR R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Who should use the R&R Subaward Budget Attachment(s) Form?

The R&R Subaward Budget Attachment(s) Form is required if you have a subaward/consortium and are using the M.300 - R&R Budget Form.

Do not use this form if you are using the PHS Modular Budget Form or if you do not have a subaward/consortium.

Each consortium recipient organization that performs a substantive portion of the project must complete an R&R Subaward Budget Attachment, including the Budget Justification section.

Consortium/Contractual F&A Costs:

NIH policy provides for the exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. However, you must include the full cost of subaward/consortium in the Subawards/Consortium Costs field (M.300 - R&R Budget Form, Section F. Other Direct Costs, Question 5). If a subaward/consortium is not performing a substantive portion of the project, they do not need to complete an R&R Subaward Budget Form; however, their costs must be included in the prime recipient's R&R Budget Form. All F&A costs count toward the direct cost limit.

Refer to the NIH Grants Policy Statement, Section 2.3.7.1: Applications That Include Consortium/Contractual F&A Costs for policy related to the exclusion of consortium/subaward amounts in determining whether an applicant is in compliance with a direct cost limitation.

Applicants should document how their budget falls below the direct cost limit in their Budget Justification on the R&R Subaward Budget Form.

Note on Project Roles for Consortium Lead Investigators:

It is appropriate and expected that someone may serve as the consortium lead investigator responsible for ensuring proper conduct of the project or program at each subaward or consortium site.

Unless you are submitting your application under the multiple PD/PI policy, consortium lead investigators are NOT considered PD/PIs for the "Project Role" field. This individual should be assigned some other project role on the M.300 - R&R Budget Form and in the M.240 – R&R Senior/Key Person Profile (Expanded) Form. However, the project role of "PD/PI" should be used for a consortium lead investigator if they also serve as PD/PI for the entire application under the multiple PD/PI policy.

Using the R&R Subaward Budget Attachment(s) Form:

The location of the R&R Subaward Budget Attachment(s) Form may vary with the type of submission (e.g., under an "Optional Forms" tab).

The steps needed to include a subaward budget in your application vary by submission method. If submitting using the Grants.gov Workspace, the prime applicant can extract a copy of the R&R Budget Form from the R&R Subaward Budget Attachment(s) Form and send the extracted file to the consortium for completion. After the consortium completes the R&R Budget Form, following the instructions here and in M.300 – R&R Budget Form, the prime recipient must then upload the R&R Budget Form to the R&R Subaward Budget Attachment(s) Form.

For all submission methods, the R&R Budget Form with a "Budget Type" of Subaward/Consortium is used to collect subaward budget data. However, ASSIST and other system-to-system solutions may present a different interface than the R&R Subaward Budget Attachment Form shown here.

This form accommodates a set number of separate subaward budgets. If you need to add more subaward budgets than the form allows, include the remaining budgets as part of Budget Justification in M.300 – R&R Budget Form.

Regardless of how many subaward budgets you include, the sum of all subaward budgets (those attached within the R&R Subaward Budget Attachment(s) Form and those provided as part of the project budget's Budget Justification), must be included in M.300 - R&R Budget Form, Section F. Other Direct Costs, Question 5. Subawards/Consortium/Contractual Costs of the project budget.

Format:

All attachments, including all Subaward Budget Forms and Budget Justifications, must be PDF files. The R&R Budget Forms are already PDFs when extracted. Do not alter the format. Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.

Content:

On this R&R Subaward Budget Attachment(s) Form, you will attach the R&R Subaward Budget files for your application. Each consortium should complete the Subaward Budget(s) in accordance with the M.300 - R&R Budget Form instructions.

Submitting Subaward Budgets that are not Active for all Periods of the Prime Grant:

The R&R Budget Forms do not allow for "empty" budget periods.

Subaward/consortiums organizations should complete all budget periods in the R&R Subaward Budget Form for their subaward budgets, aligning the budget period numbers, start dates, and end dates with the budget periods of the prime grant.

Example: The prime fills out an R&R Budget Form with the following periods:

- period 1 - Jan 1, 2017 – Dec 31, 2017
- period 2 - Jan 1, 2018 – Dec 31, 2018
- period 3 - Jan 1, 2019 – Dec 31, 2019

- period 4 - Jan 1, 2020 – Dec 31, 2020
- period 5 - Jan 1, 2021 – Dec 31, 2021

The budget period numbers and dates should be the same in all the R&R Subaward Budget Forms included in the R&R Subaward Budget Attachment(s) Form.

The R&R Subaward Budget Forms include several required fields which must be completed (even for inactive periods) in order to successfully submit the application. Provide the following information for inactive budget periods in subaward/consortium budgets:

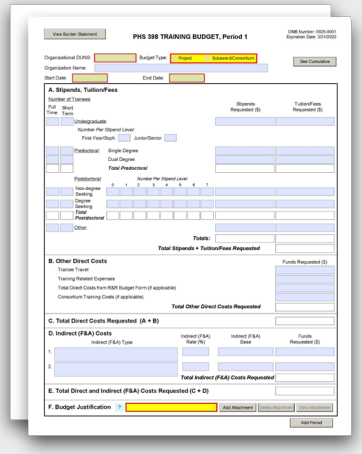
- Unique Entity Identifier
- Budget Type = Subaward/Consortium
- Budget Period Start/End Dates (align with budget periods and dates of the prime budget)
- In Question "A: Senior/Key Person," provide a single entry including the following:
    - PD/PI or subaward lead First and Last names
    - Project Role (may default to PD/PI; can be adjusted as needed)
    - Calendar Months = .01 (smallest amount effort allowed in the field)
    - Requested Salary = $0
    - Fringe Benefits = $0
- Explanation of the inactive budget periods in the Budget Justification of the subaward/consortium's R&R Subaward Budget Form

M.330 - PHS 398 Training Budget Form

The PHS 398 Training Budget Form is used only for Training applications (e.g., T15, T32, T34, T35, T36, T90) and Multi-project applications with a training component.

The PHS 398 Training Budget Form is not applicable for the K12, T37, D43, D71, or U2R activity codes. Applicants to these activity codes should follow the instructions for the R&R Budget Form and the instructions in the NOFO (if applicable).

For current stipend levels and allowable costs, refer to the relevant NOFO, NIH's Research Training & Career Development website, or consult the PHS awarding component.



View larger image

Quick Links

Who should use the PHS 398 Training Budget Form?

Use this form if you will be submitting certain types of Training Applications (e.g., T15, T32, T34, T35, T36, or T90), regardless of the amount of the requested budget.

If you are requesting a budget with $500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting the application. For more information on applications that request $500,000 or more in direct costs, see the NIH Grants Policy Statement, Section 2.3.7.2: Acceptance for Review of Unsolicited Applications Requesting $500,000 or More in Direct Costs.

Certain types of Training Applications, such as K12, T37, D43, D71, and U2R, do not use the PHS 398 Training Budget Form. These applications use the R&R Budget Form.

Note on Subawards/Consortiums: If you have a subaward/consortium, you must use the PHS 398 Training Subaward Budget Attachment(s) Form in conjunction with the PHS 398 Training Budget Form.

The prime must extract the PHS 398 Training Subaward Budgets from the PHS 398 Training Subaward Budget Attachment(s) Form and send the extracted file to the subaward/consortium. The consortium should complete the PHS 398 Training Subaward Budget, following the instructions here and in M.340 – PHS 398 Training Subaward Budget Attachment(s) Form.

Using the PHS 398 Training Budget Form:

You must complete a separate training budget for each budget period requested. The form will generate a cumulative budget for the total project period. If no funds are requested for a required field, leave the field blank.

You must round to the nearest whole dollar amount in all dollar fields.

Introductory Fields

Unique Entity Identifier (UEI):

This field is required. This field may be pre-populated from the SF 424 (R&R) Form and should reflect the UEI of the applicant organization.

Budget Type:

This field is required. Check the appropriate box for your budget type, following these guidelines.

Project: The budget being requested is for the primary applicant organization.

Subaward/Consortium: The budget being requested is for the subaward/consortium organization(s). **Note:** Separate budgets are required only for subaward/consortium organizations that perform a substantive portion of the project.

If you are preparing an application that includes a subaward/consortium, in addition to completing this form, also see M.340 – PHS 398 Training Subaward Budget Attachment(s) Form.

Organization Name:

This field may be pre-populated from the M.200 - SF 424 (R&R) Form.

Start Date:

This field is required and may be pre-populated from the M.200 - SF 424 (R&R) Form. Enter the requested/proposed start date of the budget period. For period 1, the start date is typically the same as the Proposed Project Start Date on the SF 424 (R&R) Form.

End Date:

This field is required. Enter the requested/proposed end date of the budget period.

A. Stipends, Tuition/Fees

Number of Trainees

Enter the number of trainees for each category (undergraduate, predoctoral, postdoctoral, and other), distinguishing between full-time training positions (i.e., a full year of training) and short term trainees.

Note that some programs do not allow all categories of trainees (e.g., undergraduates are not eligible for T32 applications). Refer to your NOFO regarding the eligible types of trainees for your specific application.

- For undergraduate trainees: list separately the number that will be at the First-Year/Sophomore stipend level and the number that will be at the Junior/Senior stipend level in the boxes provided.
- For predoctoral trainees: list separately the number that will be pursuing single degrees and the number that will be pursuing dual degrees in the boxes provided. The "Total Predoctoral" fields will be automatically calculated.
- For postdoctoral trainees: list separately the number that are non-degree seeking and the number that are degree seeking in the boxes provided. If a category (non-degree seeking or degree seeking) contains various stipend levels (e.g., for varying levels of postdoctoral experience or for varying appointment periods), itemize the number of postdoctoral trainees by stipend level in the boxes provided. The "Total Postdoctoral" fields will be automatically calculated.

Stipends Requested ($)

Enter the **total** stipend amount requested for each trainee type.

For current stipend levels and allowable costs, refer to the NOFO or consult the PHS awarding component. For more information, see the NIH's Research Training and Career Development website.

The "Total Stipends Requested" field will be automatically calculated.

Tuition/Fees Requested ($)

Enter the **total** tuition/fees requested for each trainee type.

See the NIH Grants Policy Statement, Section 11.3.8: Allowable and Unallowable Costs for NIH policy regarding payment of tuition and fees.

Tuition at the postdoctoral level is limited to that required for specified courses that are to be described in Section F. Budget Justification and may depend on whether the program supports postdoctoral individuals in formal degree-granting training.

The "Total Tuition/Fees Requested" field will be automatically calculated.

You should request full needs for tuition and fees. The awarding component will determine the amount of tuition and fees to be provided according to the policies current at the time of award. The formula currently in effect will be applied by the NIH awarding component at the time an award is calculated. Do not include health insurance in the tuition/fees fields.

Total Stipends + Tuition/Fees Requested

This total will be automatically calculated.

B. Other Direct Costs

Enter the total funds requested for Trainee Travel and Training Related Expenses (TRE). If applicable, enter the Total Direct Costs from the R&R Budget Form and Consortium Training Costs.

Trainee Travel

Enter the total funds requested for trainee travel in the "Trainee Travel" field.

Some NIH awarding components provide a pre-determined amount for travel for each full time trainee. Refer to the NOFO and/or contact the awarding component to determine the amount

provided for travel and enter it here. If the awarding component does not provide a pre-determined amount, enter the requested amount here and provide an explanation in Section F. Budget Justification, stating the purpose of any travel, giving the number of trips involved, the destinations, and the number of trainees for whom funds are requested. PHS policy requires coach class air travel be used. Justify any foreign travel in detail, describing its importance to the training experience.

Training Related Expenses

Enter the total funds requested for TRE. You must base your requested amount on the number of trainees at the predetermined rate.

Funds to defray other costs of training, such as health insurance, staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the amounts specified in the NOFO and in the NIH Grants Policy Statement, Section 11.3.8.4: Training-Related Expenses for each predoctoral and postdoctoral trainee.

Health insurance may be covered by TRE only to the extent that the same health insurance fees are charged to non-federally-supported students and postdoctoral fellows.

TRE will be awarded as a lump sum. No further itemization or explanation is required in Section F. Budget Justification.

The awarding component will apply the TRE level established for institutional programs for the relevant fiscal year at the time of award.

Total Direct Costs from R&R Budget Form (if applicable)

Certain NOFOs allow funds to cover direct costs for items other than those specified above. Use the R&R Budget Form to submit those costs. The Total Direct Costs from the R&R Budget Form (M.300 - R&R Budget Form, Section G. Direct Costs) should be inserted here. This line should not include any indirect costs.

Additional Instructions for Multi-project:

Skip the "Total Direct Costs from R&R Budget Form" field, as Kirschstein-NRSA Training components do not include the R&R Budget Form.

Consortium Training Costs (if applicable)

If training occurs at more than oneorganization and there is a transfer of funds between organizations, you must complete the M.340 - PHS 398 Training Subaward Budget Attachment(s) Form. Total the direct costs from the Training Subaward Budget Attachment Forms and insert the total here. The applicant organization is responsible and accountable for any arrangements, expenditures, and submission of all required application forms when more than one organization is involved in the research training program.

Total Other Direct Costs Requested

This total will be automatically calculated based on the sum of the funds requested in "B. Other Direct Costs."

C. Total Direct Costs Requested (A+B)

This total will be automatically calculated based on the sum of the funds requested in both "A. Stipends, Tuition/Fees" and "B. Other Direct Costs."

D. Indirect (F&A) Costs

Indirect costs (Facilities & Administrative [F&A] costs) are defined as costs that are incurred by a recipient for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. See the NIH Glossary's definition of Indirect Costs.

Equipment and consortium costs are also excluded from the F&A costs on those training grants where TRE are not calculated and awarded on a lump-sum basis, such as the Maximizing Access to Research Careers Program (MARC).

State and local government agencies will receive the full F&A cost rate.

For more information:

You are encouraged to visit the following Division of Financial Advisory Services (DFAS) Websites or call DFAS staff at 301-496-2444 for guidance: Main DFAS website, DFAS Frequently Asked Questions. The following website has a listing of unallowable and unallocable costs and the related Federal Acquisition Regulation (FAR) citation for each: NIH Office of Management's Unallowable/Unallocable Cost.

Indirect (F&A) Type:

Enter "F&A."

Indirect (F&A) Rate (%):

Enter "8."

Facilities and Administrative (F&A) costs under Institutional Kirschstein-NRSA awards, other than those issued to U.S., state, or local government agencies, will be awarded at 8%.

State and local government agencies should enter their full F&A cost rate.

Indirect (F&A) Base ($):

Enter the sum of the stipends and the Total Other Direct Costs requested, regardless of whether those direct costs were listed on the PHS 398 Training Budget Form or on the R&R Budget Form. Indirect costs are not paid on Tuition/Fees, equipment, or sub-grants and contracts in excess of $25,000.

Funds Requested ($):

Enter the product of Indirect (F&A) Rate and the Indirect (F&A) Base. Refer to the NIH Grants Policy Statement, Section 7.4: Reimbursement of Facilities and Administrative Costs for more information.

E. Total Direct and Indirect (F&A) Costs Requested (C+D)

This total will be automatically calculated based on the sum of the "C. Total Direct Costs Requested" and "D. Total Indirect (F&A) Costs Requested" fields.

F. Budget Justification

A Budget Justification attachment is required.

Attach one file for the entire project period. Hyperlinks and URLs are not allowed unless specified in the funding opportunity.

Explain in detail the composition of any of the above costs, as necessary, according to the guidelines listed here:

- Itemize tuition and individual fees. If tuition varies, (e.g., in-state, out-of-state, student status) list these separately. Do not include health insurance in the tuition and fees category.
- If tuition is requested for postdoctoral trainees, the specific courses or formal degree-granting program must be described.
- If the awarding component does not provide a pre-determined amount for travel for each full time trainee, explain the requested amount and describe the purpose of any travel, indicating the expected number of trips involved, the likely destinations, and the number of trainees for whom funds are requested, bearing in mind that PHS policy requires coach class air travel be used.
- Any foreign travel must be justified in detail. Describe its importance to the training experience and how those opportunities differ from and complement those offered by the recipient organization. Also describe the relationship of the proposed off-site training experience to the career stage of the recipient.
- Justify the number of training slots (e.g., predoctoral and / or postdoctoral) requested. For postdoctoral training slots, justify the stipend levels requested.

Note for Applicants Using both the PHS 398 Training Budget Form and the R&R Budget Form: Generally, the Budget Justification included in the PHS 398 Training Budget Form should reflect only funds requested on the PHS 398 Training Budget Form. When the R&R Budget Form is also used, two separate Budget Justifications are required, each covering the costs requested in the respective Budget Form.

PHS 398 Training Budget, Cumulative Budget

All values on this form are automatically calculated, and the fields are pre-populated. They present the summations of the amounts you entered previously for each of the individual budget periods. Therefore, no data entry is allowed or required to complete the "Cumulative Budget" section.

If any of the amounts displayed on this form appear to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such corrections, you will need to revisit the appropriate budget period form(s).

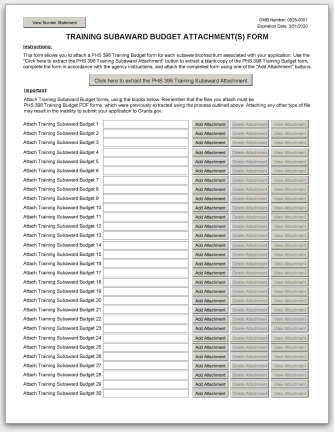
M.340 - PHS 398 Training Subaward Budget Attachment(s) Form

The PHS 398 Training Subaward Budget Attachment(s) Form is used for applications with a subaward or consortium.

This form is required only when the prime recipient is submitting a PHS 398 Training Budget Form and has subaward / consortium budgets.

Applicants using the R&R Budget Form should see M.300 - R&R Budget Form.

View larger image


TRAINING SUBAWARD BUDGET ATTACHMENT(S) FORM

Who should use the PHS 398 Training Subaward Budget Attachment(s) Form?

The PHS 398 Training Subaward Budget Attachment(s) Form is required if you have a subaward/consortium and are using the PHS 398 Training Budget Form.

Do not use this form if you do not have a subaward/consortium.

Each subaward/consortium that performs a substantive portion of the project must complete a Training Subaward Budget, including the Budget Justification section. For most programs, this is not common but is usually encountered when a portion of the training program takes place at a site other than the applicant organization via a collaborative or consortium arrangement. In such situations, the applicant organization is responsible and accountable for acceptable training arrangements, expenditure of funds, and submission of all required forms.

Consortium/Contractual F&A Costs:

NIH policy provides for the exclusion of consortium / contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. However, you must include the full cost of consortium / subawards in the Subawards / Consortium Costs field. If a subaward / consortium is not performing a substantive portion of the project, they do not need to complete a Training Subaward Budget; however, their costs must be included in the prime recipient's Training Budget Form. All F&A costs count toward the direct cost limit.

See the NIH Grants Policy Statement, Section 2.3.7.1: Applications That Include Consortium/Contractual F&A Costs for policy related to the exclusion of consortium/subaward amounts in determining whether an applicant is in compliance with a direct cost limitation.

Applicants should document how their budget falls below the direct cost limit in the Budget Justification of the Training Subaward Budget.

Note on Project Roles for Consortium Lead Investigators:

It is appropriate and expected that someone may serve as the consortium lead investigator responsible for ensuring proper conduct of the project or program at each subaward or consortium site.

Unless you are submitting your application under the multiple PD/PI policy, consortium lead investigators are NOT considered PD/PIs for the "Project Role" field. This individual should be assigned some other project role on the PHS 398 Training Budget Form and in the M.240 – R&R Senior/Key Person Profile (Expanded) Form. However, the project role of "PD/PI" should be used for a consortium lead investigator if they also serve as PD/PI for the entire application under the multiple PD/PI policy.

Using the PHS 398 Training Subaward Budget Attachment(s) Form:

The location of the PHS 398 Training Subaward Budget Attachment(s) Form may vary with the type of submission (e.g., under an "Optional Forms" tab).

The steps needed to include a subaward budget in your application vary by submission method. If submitting using the Grants.gov Workspace, the prime applicant can extract a copy of the Training Subaward Budget Form from the Training Subaward Budget Attachment(s) Form and send the extracted file to the consortium for completion. After the consortium completes the Training Subaward Budget Form, following the instructions here and in M.330 – PHS 398 Training Budget Form, the prime recipient must then upload all the Training Subaward Budget Forms to the Training Subaward Budget Attachment(s) Form.

For all submission methods, the Training Subaward Budget Form with a "Budget Type" of Subaward/Consortium is used to collect subaward budget data. However, ASSIST and other system-to-system solutions may present a different interface than the Training Subaward Budget Attachment Form shown here.

This form accommodates a set number of separate subaward budgets. If you need to add more subaward budgets than the form allows, include the remaining budgets as part of the "Section F. Budget Justification" of the project budget.

Regardless of how many subaward/consortium budgets you include, the sum of ALL subaward/consortium budgets (those attached within the PHS 398 Training Subaward Budget Attachment(s) Form and those provided as part of the parent budget's Budget Justification), must be included in the M.330 - PHS 398 Training Budget, Part B. Consortium Training Costs.

Format:

All attachments, including all Training Subaward Budget Forms and all Budget Justifications, must be PDF files. The Training Budget Forms are already PDFs when extracted. Do not alter the format. Hyperlinks and URLs are not allowed unless specified in the funding opportunity.

Content:

On this PHS 398 Training Subaward Budget Attachment(s) Form, you will attach the Training Subaward Budget files for your application. Each subaward/consortium will complete the Subaward Budget in accordance with the M.330 - PHS 398 Training Budget Form instructions.

Submitting Subaward Budgets that are not Active for all Periods of the Prime Grant:

The Training Budget Forms do not allow for "empty" budget periods.

Subaward/consortium organizations should complete all budget periods in the Training Subaward Budget Form for their subaward budgets, aligning the budget period numbers, start dates, and end dates with the budget periods of the prime grant.

Example: The prime fills out a PHS 398 Training Budget Form with the following periods:

- period 1 - Jan 1, 2017 – Dec 31, 2017
- period 2 - Jan 1, 2018 – Dec 31, 2018
- period 3 - Jan 1, 2019 – Dec 31, 2019
- period 4 - Jan 1, 2020 – Dec 31, 2020
- period 5 - Jan 1, 2021 – Dec 31, 2021

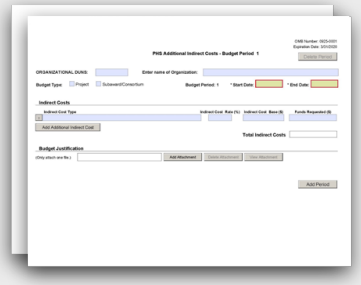
The budget period numbers and dates should be the same in all Training Subaward Budgets included in the PHS 398 Training Subaward Budget Attachment(s) Form.

The PHS 398 Training Subaward Budget Forms include several required fields which must be completed (even for inactive periods) in order to successfully submit the application. Provide the following information for inactive budget periods in subaward/consortium budgets:

- Unique Entity Identifier (UEI)
- Budget Type = Subaward/Consortium
- Budget Period Start/End Dates (align with budget periods and dates of the prime budget)
- Explanation of the inactive budget periods in the Budget Justification (of the subaward/consortium's Training Subaward Budget)

M.350 - PHS Additional Indirect Costs Form

The PHS Additional Indirect Costs Form is used only for multi-project applications. The applicant organization responsible for the Overall Component should use this form to detail its first $25,000 F&A costs on each subaward organization that leads a component.



View larger image

Quick Links

Introductory Fields

Indirect Costs

Budget Justification

PHS Additional Indirect Cost - Cumulative Budget

Who should use the PHS Additional Indirect Costs Form:

The PHS Additional Indirect Costs Form is used only for multi-project applications.

The applicant organization responsible for the Overall Component should use this form to detail its first $25,000 indirect (Facilities and Administrative [F&A]) costs on each subaward organization that leads a component.

Introductory Fields

Unique Entity Identifier (UEI):

This field is required. Enter the UEI of the applicant organization.

Enter name of Organization:

This field may be pre-populated from the SF 424 (R&R) Form. Enter the name of the organization.

Budget Type:

This field is required. "Project" should be selected.

Budget Period:

This field is required.

Identify the specific budget period (for example, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10).

Start Date:

This field is required and may be pre-populated from the SF 424 (R&R) Form. Enter the requested/proposed start date of the budget period.

End Date:

This field is required. Enter the requested/proposed end date of the budget period.

Indirect Costs

Indirect Cost Type:

Enter the type of indirect cost (e.g., Salary & Wages, Modified Total Direct Costs, etc.) and whether the cost is off-site. If more than one rate or base is involved for a given type of indirect cost, then list them as separate entries. If you do not have a current indirect (F&A) rate(s) approved by a federal agency, indicate "None—will negotiate" and include information for a proposed rate. Use the Budget Justification in this form if additional space is needed.

Indirect Cost Rate (%):

Enter the most recent indirect cost rate(s) established with the cognizant federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/oversight agency and are selected for an award, you must submit your indirect rate proposal to the NIH awarding IC or to the PHS awarding office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency.

This field should be entered using a rate such as "55.5."

Indirect Cost Base ($):

Enter the amount of the base for each indirect cost type.

Funds Requested ($):

Enter the funds requested for each indirect cost type.

See the NIH Grants Policy Statement, Section 7.4: Reimbursement of Facilities and Administrative Costs for more information.

Total Indirect Costs:

This total will be automatically calculated from the "Funds Requested" column.

Budget Justification

The "Budget Justification" attachment is required.

Attach only one file. Attach this information as a PDF. Hyperlinks and URLs are not allowed unless specified in the funding opportunity.

Use the Budget Justification to provide the additional information requested in each budget category identified above and any other information that supports the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support, and other direct cost categories.

PHS Additional Indirect Cost – Cumulative Budget

Indirect Costs Totals ($):

All values on this form are automatically calculated and the fields pre-populated. They present the summations of the amounts you entered in the "Indirect Costs" section above, for each of the

individual budget periods. Therefore, no data entry is allowed or required to complete this "Cumulative Budget" section.

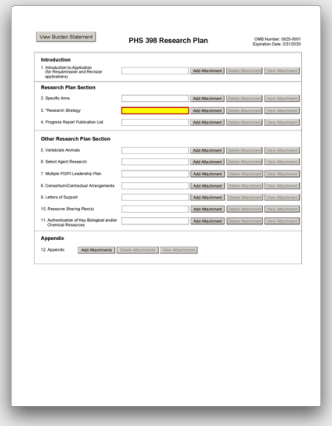
If any of the amounts displayed on this form appear to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such corrections, you will need to revisit the appropriate budget period form(s).

M.400 - PHS 398 Research Plan Form

The PHS 398 Research Plan form is used only for research, multi-project, and SBIR/STTR applications.

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

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



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Quick Links

Your application should represent a sound approach to the investigation of an important biomedical research, behavioral research, technological, engineering, or scientific question, and be worthy of support under the stated criteria of the NOFO. It should be self-contained and written with the care and thoroughness accorded to papers for publication.

Review the application carefully to ensure you have included information essential for evaluation. The scientific and technical merit of the proposed research is the primary concern for all research supported by the National Institutes of Health (NIH) and other PHS agencies.

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

Who should use the PHS 398 Research Plan Form:

Use the PHS 398 Research Plan Form only if you are submitting a research, multi-project, or SBIR/STTR application.

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 and Revision applications)

Who must complete the "Introduction to Application" attachment:

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

See NIH Types of Applications for descriptions.

Format:

Follow the page limits for the introduction in the NIH Table of Page Limits unless otherwise specified in the NOFO.

Attach this information as a PDF file. See NIH's Format Attachments page. Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

Content:

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

> Note: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the introduction.

Competing Revisions: See specific instructions on the content of the introduction on the NIH's Competing Revisions page.

Additional Instructions for Multi-project:

Overall Component: The “Introduction” attachment is required for all resubmission and revision applications.

Other Components: The "Introduction” attachment is optional for resubmissions and revisions applications. Although the “Introduction” attachment is optional, you may get a system warning if there is no attachment.

Research Plan Section

2. Specific Aims

Who must complete the "Specific Aims" attachment:

The “Specific Aims” attachment is required unless otherwise specified in the NOFO.

Format:

Follow the page limits for the Specific Aims in the NIH Table of Page Limits unless otherwise specified in the NOFO. A “Specific Aims” attachment that exceeds the page limit will be flagged as an error by the Agency upon submission.

Attach this information as a PDF file. See NIH's Format Attachments page. Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

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).

Additional Instructions for Multi-project:

Overall Component: The "Specific Aims" attachment is required.

Other Components: The "Specific Aims" attachment is required.

3. 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 NOFO. 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. Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

Content:

Organize the Research Strategy in the specified order and use the instructions provided below unless otherwise specified in the NOFO. Start each section with the appropriate heading – Significance, Innovation, Approach.

Cite published experimental details in the Research Strategy attachment and provide the full reference in M.220 - R&R Other Project Information Form, Bibliography and Reference Cited.

Note for Applications Proposing the Use of Human Fetal Tissue: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application you must include specific information in the Approach section of the Research Strategy attachment. See specific instructions below in Section 3. Approach. This information must be provided regardless of whether Human Subjects research is proposed or not.

Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions.

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

- Do not duplicate information in the Research Strategy and the PHS Human Subjects and Clinical Trials Information form. Use the Research Strategy attachment to discuss the overall strategy, methodology, and analyses of your proposed research. Use the PHS Human Subjects and Clinical Trials Information form to provide detailed information for human subjects studies and clinical trials.
- The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and individuals across the lifespan; protection and monitoring plans; and statistical design and power.
- You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy (e.g., see Question 2.4 Inclusion of Women and Minorities).

Note for Applicants with Multiple Specific Aims: You may address the Significance, Innovation, 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.
- Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Additional Instructions for Multi-project:

Overall and Other Components: Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

2. Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, and reference any Resource Sharing Plans and the Data Management and Sharing (DMS) Plan, as appropriate. Resources and tools for rigorous experimental design can be found at the Enhancing Reproducibility through Rigor and Transparency website.
- 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.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to the NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for additional information.
- Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment below.
- If 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.

Special Instructions for Applications Proposing the Use of Human Fetal Tissue: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application

- Use the specific heading: "Human Fetal Tissue Research Approach".
- Describe the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.
- Justify the use of HFT in the proposed research by indicating the following:
    - Why the research goals cannot be accomplished by using an alternative to HFT.
    - What methods were used (e.g. literature review, preliminary data) to determine that alternatives could not be used.
    - Results from a literature review used to provide justifications.
    - Plans for the treatment of HFT and the disposal of HFT when research is complete.
    - Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained.

Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions..

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.

Preliminary Studies for New Applications:

For new applications, include information on preliminary studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and can help to establish the likelihood of success of the proposed project. Early stage investigators should include preliminary data.

Progress Report for Renewal and Revision Applications:

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

For renewal/revision applications, 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 definition for clinical research. Use the Progress Report section to discuss, but not duplicate information collected elsewhere in the application.

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

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided.

4. Progress Report Publication List

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

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

SeeTypes of Applications for descriptions.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs in this section is not allowed unless specified in these instructions or in the funding opportunity.

Content:

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 citation requirements. See related Interim Research Product FAQ 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 each of the following:

- Articles that fall under the Public Access Policy,
- Articles that were authored or co-authored by the applicant and arose from NIH support,
- Articles that were authored or co-authored by the applicant and arose from AHRQ funding provided after February 19, 2016 (see the 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 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. Active hyperlinks are not allowed.

Additional Instructions for Multi-project:

Overall and Other Components: If you include a "Progress Report Publication List" attachment, you can include it in either the Overall Component or within each Other Component, but do not attach the same information in multiple locations.

Other Research Plan Section

5. 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 M.220 - R&R Other Project Information Form.

Format:

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

Do not use this 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
- See the NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirements (an applicable Animal Welfare Assurance will be required if the recipient organization does not have one)

Additional Instructions for Multi-project:

Overall Component: The "Vertebrate Animals" attachment is optional unless specifically requested in the NOFO.

Other Components: Complete the "Vertebrate Animals" section if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the M.220 - R&R Other Project Information Form.

6. 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 and Plant Health Inspection Service (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 4.1.24.1.1: 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 organization, 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.

7. Multiple PD/PI Leadership Plan

Who must complete the "Multiple PD/PI Leadership Plan" attachment:

Any applicant who designates multiple PD/PIs (on the M.240 - R&R Senior/Key Person Profile (Expanded) Form) must include a Multiple PD/PI Leadership Plan. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the M.240 - R&R Senior/Key Profile (Expanded) Form, even those at organizations other than the applicant organization.

Do not submit a Multiple PD/PI Leadership Plan if you are not submitting a multiple PD/PI application.

Additional Instructions for Multi-project:

Overall Component: The "Multiple PD/PI Leadership Plan" attachment is required if more than one PD/PI is specified on the Overall Component's M.240 - R&R Senior/Key Profile (Expanded) Form.

Format:

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

Content:

A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

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

Resubmission Applications: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for

the change in the progress report within the research strategy and include the required Multiple PD/PI Leadership Plan.

For more information:

For background information on the multiple PD/PI initiative, see NIH's Multiple Principal Investigators page.

8. Consortium/Contractual Arrangements

Who must complete the "Consortium/Contractual Arrangements" attachment:

Include a "Consortium/Contractual Arrangements" attachment if you have consortiums/contracts in your budget.

Format:

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

Content:

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the recipient.

Note: The signature of the authorized organization representative in M.200 - SF 424 (R&R), Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

> *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.*

For more information:

Refer to the NIH Grants Policy Statement, Section 15: Consortium Agreements for more information.

Additional Instructions for Multi-project:

Overall and Other Components: Unless otherwise specified in the NOFO, you have the option to:

- include a single consolidated "Consortium/Contractual Arrangements" attachment in the Overall Component, or
- include component-specific "Consortium/Contractual Arrangements" attachment (s) within the components that include subawards, or
- include a "Consortium/Contractual Arrangements" attachment in the Overall Component and include component-specific attachments within the components that include subawards. Each filename must be unique.

9. Letters of Support

Format:

Combine all letters of support into a single PDF file and attach this information here. Do not place these letters in the Appendix.

Follow the attachment guidelines on NIH's Format Attachments page. Use of hyperlinks and URLs in Letters of Support is not allowed unless specified in the funding opportunity.

Content:

Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.

Letters should stipulate expectations for co-authorship, and whether cell lines, samples, or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.

For consultants, letters should include rate/charge for consulting services and level of effort / number of hours per budget period anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.

Material Transfer Agreements may be included in this section.

Letters must focus on the topics listed above and not contain data / figures / tables / graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy section of the application. Letters of Support serve to describe terms of a collaboration or consultation and also are not de facto letters of reference from persons not actively participating in the project. Applications with letters containing such excess information may be withdrawn from the review process.

Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

Do not include consultant biographical sketches in the "Letters of Support" attachment, as consultant biosketches should be in the "Biographical Sketch" section.

Additional Instructions for Multi-project:

Overall and Other Components: Unless specific instructions are provided in the NOFO, applicants have the option of including the "Letters of Support" attachment in the Overall Component, Other Components, or both. To avoid duplication, each letter should appear only once in the application. Letters that apply to the entire application (or to multiple components) should be presented in the Overall Component as a single PDF, while letters that apply only to a particular individual component should be presented in that component as a single PDF.

10. Resource Sharing Plan(s)

Note: Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan.

Format:

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

Content:

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.

Research Tools:

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. For more information, see the Research Tools Policy on the NIH Scientific Data Sharing Website and the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

11. Other Plan(s)

Who Must Complete This Section: Refer to the list of NIH activity codes subject to the DMS Policy and your NOFO to determine if your application is required to provide an attachment and address a Data Management and Sharing (DMS) Plan. Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan. Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.

The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan.

Applicants subject to both the NIH Data Management and Sharing Policy and the NIH Genomic Data Sharing Policy must attach a single Plan including elements for both policies. For more on applicability of each policy, see research subject to the NIH Data Management and Sharing Policy and the research subject to the NIH Genomic Data Sharing Policy.

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

A sample format is provided on the Data Management and Sharing Plan Format Page to assist applicants with preparation of this attachment. Do not include hyperlinks in this attachment. Recommended not to exceed two pages.

Content: Follow the expectations of the NIH Policy for Data Management and Sharing and address the Elements of an NIH Data Management and Sharing Plan described below.

Additional expectations: A Data Management and Sharing Plan should reflect the proposed approach at the time the application is prepared. For some programs and data types, NIH and/or

NIH Institutes, Centers, Offices, or programs have developed additional data sharing requirements (e.g., specifying which scientific data to share, relevant standards, repository selection, timelines) that apply and should be reflected in a Plan. These additional requirements may be listed on NIH Institute and Center Data Sharing Policies or in specific Notice of funding opportunities. Note that some NIH Institutes, Centers, Officers, or programs have developed additional expectations for sharing genomic data that may be listed on NIH Institute and Center Genomic Data Sharing Expectations or in specific funding opportunities.

Elements of a Data Management and Sharing Plan:

Data Type: Briefly describe the scientific data to be managed, preserved, and shared, including a general summary of the types and estimated amount of scientific data to be generated and a description of which scientific data from the project will be preserved and shared as well as the rationale for doing so. Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Related Tools, Software and/or Code: State whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software. If specialized tools or software are needed, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Standards: State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources (e.g., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation), and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Data Preservation, Access, and Associated Timelines: Provide plans and timelines for data preservation and access, including the name of the repository(ies) where scientific data and metadata arising from the project will be archived (do not include hyperlinks); how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools; and when (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) the scientific data will be made available to other users (e.g., the larger research community, institutions, and/or the broader public) and for how long. See Selecting a Data Repository on the NIH Scientific Data Sharing website.

Access, Distribution, or Reuse Considerations: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research, consistent with privacy, security, informed consent, and proprietary issues. Describe and justify any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements, or any other considerations that may limit the extent of data sharing. See Data Management & Sharing Policy FAQ for examples of justifiable reasons for limiting sharing of data. State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

Genomic Data Sharing Policy: For proposed research subject to the GDS Policy, state whether data, including genomic summary results, will be made available through controlled or unrestricted access; see instructions for describing Genomic Summary Results in Data Management and Sharing Plans.

If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures). See NIH's Scientific Data Sharing page for additional information on protecting human research participant privacy when sharing data.

Genomic Data Sharing Policy: For proposed research generating human genomic data within the scope of the GDS Policy, applicants should complete the Data Management and Sharing Plan anticipating sharing according to the assurances of the Institutional Certification.

If there is any element of the Institutional Certification that the institution (in consultation with the IRB) has determined cannot be met, please state which element and provide a detailed explanation for why the element cannot be met. In such cases, the data management and sharing plan should describe how genomic data will be shared to the maximal extent possible (for example, sharing data in a summary format).

Oversight of Data Management and Sharing: Describe how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom at the applicant institution (e.g., titles, roles).

For more information on developing a Data Management and Sharing Plan, see Writing a Data Management and Sharing Plan on the NIH Scientific Data Sharing website.

For more information on the DMS Policy, including expectations for data management and sharing, protecting research participant privacy, and identifying data repositories, see the NIH Data Management and Sharing Policy on the NIH Scientific Data Sharing website and the NIH Grants Policy Statement, Section 8.2.3.1: Data Sharing Policy. See also Data Management & Sharing Policy FAQ for additional information on the DMS Policy on these and other topics.

For more information on the GDS Policy see the NIH Genomic Data Sharing Policy on the NIH Scientific Data Sharing website and the NIH Grants Policy Statement, Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS).

Additional Instructions for Multi-project:

Overall Component Include a single consolidated "Data Management and Sharing Plan" in the Overall Component.

Other Components: Do not include a "Data Management and Sharing Plan" within other components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment in the Overall Component.

12. Authentication of Key Biological and/or Chemical Resources

Format:

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

Content:

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

For more Information:

Key biological and/or chemical resources are characterized as follows.

- Key biological and/or chemical resources may or may not have been generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
- See NIH's page on Rigor and Reproducibility for more information.

Appendix

13. Appendix

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

Additional Instructions for Multi-project:

Overall and Other Components: The "Appendix" attachment is optional.

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 filenames 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 NOFO 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 NOFOs may have different instructions for the Appendix. Always follow the instructions in your NOFO 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 NOFO.

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 NOFO. For example, do not include material transfer agreements (MTA) in the appendix unless otherwise specified in the NOFO.

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

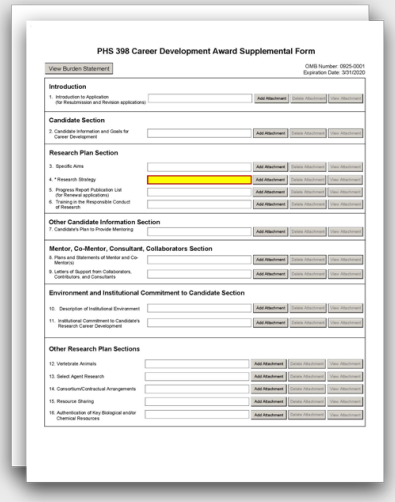
M.410 - PHS 398 Career Development Award Supplemental Form

The PHS 398 Career Development Award Supplemental Form is used only for career development applications and multi-project applications with an "Indiv. Career Dev" Component.

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

See NIH's Reference Letters page for information including instructions for referees and how to submit letters.

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



View larger image

Quick Links

Who should use the PHS 398 Career Development Award Supplemental Form:

Use the PHS 398 Career Development Award Supplemental Form only if you are submitting a career development application or a multi-project application that has an "Indiv. Career Dev" Component.

Some sections of the PHS 398 Career Development Award Supplemental Form are required for all career development award applications, while others are to be used only when required by the NOFO.

Read all the instructions in the NOFO before completing this section to ensure 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 and Revision applications)

Who must complete the "Introduction to Application" attachment:

An "Introduction to Application" attachment is required only if the type of application is resubmission or revision. An introduction is not allowed for new or renewal applications.

See Types of Applications for descriptions.

Format:

Follow the page limits for the Introduction in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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.

Competing Revisions: See specific instructions on the content of the Introduction on the NIH's Competing Revisions page.

Additional Instructions for Multi-project:

Other Components: The "Introduction" attachment is optional for resubmissions and revisions applications. Although the "Introduction" attachment is optional, you may get a system warning if there is no attachment.

Candidate Section

2. Candidate Information and Goals for Career Development

Who must complete the "Candidate Information and Goals for Career Development" attachment:

The "Candidate Information and Goals for Career Development" attachment is required.

Format:

Follow the page limits for Candidate Information and Goals for Career Development in the NIH Table of Page Limits, unless otherwise specified in the NOFO.

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

Content:

Organize your attachment into three sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Candidate's Background, Career Goals and Objectives, and Candidate's Plan for Career

Development/Training Activities During Award Period. Also include any additional information requested in the NOFO.

Candidate's Background:

- Describe your past scientific history, indicating how the award fits into past and future research career development.
- If there are consistent themes or issues that have guided previous work, these should be made clear. Alternatively, if your work has changed direction, indicate the reasons for the change.

Career Goals and Objectives:

- Describe your short-term and long-term career development goals.
- Justify the need for the award by describing how the career development award will enable you to develop and/or expand your research career.
- If applicable (e.g., K24), describe how this award will help you to serve as a mentor to early career investigators.

Candidate's Plan for Career Development/Training Activities During Award Period:

- Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches and data analysis and interpretation.
- For non-mentored career development awards, describe any planned release from teaching, administrative, and/or clinical duties that will help you focus on your research activities, and if applicable, your mentoring activities.
- For mentored career development awards, describe any structured activities that are part of the developmental plan, such as coursework or workshops that will help you learn new techniques or develop needed professional skills.
- Briefly discuss each of the activities, other than research, in which you expect to participate.
- For each activity, other than research, explain how it relates to the proposed research and to the career development plan. Indicate the percentage of time to be dedicated to each activity by year, expressed in person months. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.
- You are encouraged to include a timeline, including plans to apply for subsequent grant support.

Research Plan Section

A Research Plan is required for all types of individual career development awards.

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

The Research Plan is a major part of the overall career development goal. It is important to relate the proposed research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan. Also describe how the research and other developmental activities will enable the candidate to launch and conduct an independent research career or enhance an established research career.

For most types of research, the Research Plan Section 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.

A Career Development Award (CDA) Research Plan is expected to be tailored to the experience level of the candidate and to allow him/her to develop the necessary skills needed 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 sole part(s) of a CDA Research Plan.

Although candidates for mentored career development awards are expected to write the Research Plan, the mentor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful. Although it is understood that CDA applications do not require the extensive detail usually incorporated into regular research grant applications, a fundamentally sound Research Plan that includes a reasonably detailed Research Strategy section should be provided.

3. Specific Aims

Who must complete the "Specific Aims" attachment:

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

Format:

Follow the page limits for the Specific Aims in the NIH Table of Page Limits, unless otherwise specified in the NOFO. A "Specific Aims" attachment that exceeds the page limit will be flagged as an error by the Agency upon submission.

Attach this information as a PDF file. 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 NOFO.

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. Start each section with the appropriate heading – Significance, Innovation, Approach.

Cite published experimental details in the Research Strategy section and provide the full reference in M.220 - R&R Other Project Information Form, Bibliography and References Cited.

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

Note for mentored CDA applications: Explain the relationship between the candidate's research on the CDA and the mentor's ongoing research program.

Note for non-mentored CDA applications: In general, non-mentored CDA applicants are expected to have independent, peer-reviewed research support. Applications should include a brief description of currently funded research, along with a more extensive description of any new research to be supported by the CDA.

Note for Applications Proposing the Use of Human Fetal Tissue:

If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application you must include specific information in the Approach section of the Research Strategy attachment. See specific instructions below in Section 3. Approach. This information must be provided regardless of whether Human Subjects research is proposed or not. These specific instructions do not apply to institutional career development applications (e.g. K12, KL2).

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 individuals across the lifespan; protection and monitoring plans; and statistical design and power.
- You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy (e.g., see Question 2.4 Inclusion of Women and Minorities).

Note for Applicants with Multiple Specific Aims: You may address the Significance, Innovation, 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.
- Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

2. Innovation

- Explain how the application challenges current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan section, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans and the Data Management and Sharing (DMS) Plan as appropriate. Resources and tools for rigorous experimental design can be found at the Enhancing Reproducibility through Rigor and Transparency website.
- 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.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for additional information.

- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research section 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.

- **Special Instructions for Applications Proposing the Use of Human Fetal Tissue:** If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application:
    - Use the specific heading: "Human Fetal Tissue Research Approach".
    - Describe the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.
    - Justify the use of HFT in the proposed research by indicating the following:
        - Why the research goals cannot be accomplished by using an alternative to HFT.
        - What methods were used (e.g. literature review, preliminary data) to determine that alternatives could not be used.
        - Results from a literature review used to provide justifications.
        - Plans for the treatment of HFT and the disposal of HFT when research is complete.
        - Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained.

    - Note: These specific instructions do not apply to institutional career development applications (e.g. K12).
    - Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions.

- 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 three sections (Significance, Innovation, and Approach) listed above.

Preliminary Studies (for New Applications):

For new applications, include information on preliminary studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application.

Progress Report (for Renewal and Revision Applications):

Most career development applicants will not complete this attachment. However, if you are required to do so, note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

For renewal/revision applications, 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 definition for clinical research. Use the Progress Report section to discuss, but not duplicate information collected elsewhere in the application.

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

5. Progress Report Publication List (for Renewal applications)

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

A "Progress Report Publication List" attachment is required only if the type of application is renewal. Most career development applicants will not complete this attachment.

See Types of Applications for descriptions.

Format:

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

Content:

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 citation requirements. See related Interim Research Product FAQ 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:

- Articles that fall under the Public Access Policy,
- Articles that were authored or co-authored by the applicant and arose from NIH support,
- Articles that were authored or co-authored by the applicant and arose from AHRQ funding provided after February 19, 2016 (see the 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 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.

Additional Instructions for Multi-project:

Overall and Other Components: If you include a "Progress Report Publication List" attachment, you can include it in either the Overall Component or within each Other Component, but do not attach the same information in multiple locations.

6. 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 the Training in the Responsible Conduct of Research in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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

Content:

Mentored CDA applications should describe a plan to acquire instruction in the responsible conduct of research (RCR).

Non-mentored (independent) CDA applications should describe a plan to obtain or provide instruction in RCR, depending on your level of experience with RCR.

Attach a description of plans for obtaining or providing instruction in RCR. This section should document prior instruction or participation in RCR training during the applicant's current career stage (including the date instruction was last completed). This section should also propose plans to either receive instruction or provide instruction (e.g., to participate as a course lecturer) to meet the frequency requirement of RCR training (see the "For more information section" below).

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 12.4.1.4: Training in the Responsible Conduct of Research.

1. **Format:** Describe the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable).
2. **Subject Matter:** Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics).
3. **Faculty Participation:** Describe the role of the mentor(s) and other faculty involvement in the instruction.
4. **Duration of Instruction:** Describe the 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.

The plan may include career stage-appropriate individualized instruction or independent scholarly activities. Instruction and activities should enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the mentor in RCR instruction must be described.

Renewal Applications: Describe the RCR instruction activities undertaken during the previous project period as well as future plans for RCR instruction.

For more information:

See the NIH Grants Policy Statement, Section 12.4.1.4: Training in the Responsible Conduct of Research.

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring

Who must complete the "Candidate's Plan to Provide Mentoring" attachment:

Include the "Candidate's Plan to Provide Mentoring" attachment only when required by the NOFO, (e.g., K05 and K24).

Format:

Follow the page limits for the Candidate's Plan to Provide Mentoring in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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

Content:

The plan should provide information about both the candidate's commitment to serve as a mentor to other investigators and the candidate's previous mentoring activities. State the candidate's proposed percent effort commitment to the mentoring plan, expressed in person months. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.

Describe proposed mentoring activities: Describe the setting for mentoring and provide information about the available pool of mentees with appropriate backgrounds and similar interests in science as the candidate. Include information sufficient for reviewers to evaluate the quality of the proposed mentoring experience, including the professional levels of mentees and the frequency and kinds of mentoring interactions between the candidate and mentees. Describe the productivity of the mentoring relationship for the scientific development of the new scientists as judged by their publications and current research activities.

Describe past mentoring activities: Include sufficient information on the candidate's past mentees so that reviewers can evaluate the quality of prior mentoring experiences. Include information such as the professional levels of mentees, and the frequency and kinds of mentoring interactions between the candidate and mentees.

Senior level (K05) candidates: Describe any financial and material support from your own funded research and research resources that will be available to your mentees.

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s)

Who must complete the "Plans and Statements of Mentor and Co-Mentor(s)" attachment:

Any candidate applying for a mentored CDA (see Summary of Career Development Award Mechanisms table) must include a "Plans and Statement of Mentor and Co-Mentor(s)" attachment.

All mentored career development applications should identify any and all co-mentors involved with the proposed research and career development program. The mentor and each co-mentor must provide a statement as described below.

Format:

Follow the page limits for the Plans and Statements of Mentor and Co-mentor(s) in the NIH Table of Page Limits unless otherwise specified in the NOFO.

The plans and statements must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page.

Content:

The mentor and co-mentor(s) (if applicable) must each document their role and willingness to participate in the project, and explain how they will contribute to the development of the candidate's research career. Each statement should include all of the following:

1. The plan for the candidate's training and research career development. Include information not only about research, but also about other developmental activities, such as seminars, scientific meetings, training in RCR, and presentations. Discuss expectations for publications over the entire period of the proposed project. Define what aspects of the proposed research project the candidate will be allowed to continue to pursue as part of his/her independent research program.
2. The source of anticipated support for the candidate's research project for each year of the award period.
3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
4. The candidate's anticipated teaching load for the award period (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.
5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. Describe the mentor's (or co-mentor's) previous experience as a mentor, including type of mentoring (e.g., graduate students, career development recipients, postdoctoral fellows), number of persons mentored, and career outcomes.

Note for co-mentor statements: Co-mentors must also address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared

with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this CDA.

Note: If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, then the mentor or a member of the mentoring team should include information in the statement to document leadership of the clinical trial (in addition to the information above). Include the following:

- Source of funding;
- ClinicalTrials.gov Identifier (e.g., NCT87654321), if applicable;
- A description of how your expertise is appropriate to guide the applicant in any proposed clinical trials research experience; and
- A statement/attestation that the mentor will be responsible for the clinical trial.
- The mentor must have primary responsibility for leading and overseeing the trial and must describe how she/he will provide this oversight (be careful not to overstate the candidate's responsibilities).
- Include details on the specific roles/responsibilities of the applicant and mentor, keeping in mind that the terms of a CDA award do not always permit the candidate to lead a clinical trial.

Do not place these statements from the mentor(s) and co-mentor(s) in the Appendix.

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

Note that letters of support are not the same as letters of reference (also known as reference letters), which are required for some K applications. For more information about letters of reference, see the NIH's Reference Letters page.

From whom are letters of support required? From whom are letters not required?

Letters of support from collaborators, contributors, and consultants will be required for any such person who will contribute to the scientific development or execution of CDA application's proposed project. Follow the requirements for letters of support as listed in the NOFO.

Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

Format:

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

Attach all appropriate letters of support. The letters must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.

Content:

Letters from consultants should include rates/charges for consulting services.

Mentored CDA applications should identify collaborators, contributors, and consultants involved with the proposed research and career development program, and not already included in the "Plans and Statements of Mentor(s) and Co-Mentor(s)" section. Letters should briefly describe their

anticipated contributions and document their role and willingness to participate in the project. The letters should also briefly describe research materials, data, guidance, or advice each person will provide.

Non-mentored CDA applications should include letters from collaborators, consultants, and contributors. Letters should list proposed roles and document their willingness to participate in the project. The letters should also briefly describe research materials, data, guidance, or advice each person will provide.

Environment andInstitutional Commitment to Candidate Section

10. Description of Institutional Environment

Who must complete the "Description of Institutional Environment" attachment:

The "Description of Institutional Environment" attachment is required.

Format:

Follow the page limits for the Description of Institutional Environment in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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

Content:

Mentored CDA applicants: Describe the institution's research and career development opportunities related to your area(s) of interest, including the names of key faculty members and other investigators relevant to your proposed developmental plan and capable of productive collaboration with the candidate. Indicate how the necessary facilities and other resources will be made available for both career enhancement and the research proposed in this application – refer to the resources description in M.220 - R&R Other Project Information Form, Facilities and Other Resources in your "Description of Institutional Environment" attachment. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

Non-mentored CDA applicants: Describe the institution's research and career development opportunities related to your area(s) of interest, including the names of other faculty members who are willing to collaborate with you. Indicate how the necessary facilities and other resources will be made available for both career enhancement and the research proposed in this application – refer to the resources description in M.220 - R&R Other Project Information Form, Facilities and Other Resources in your "Description of Institutional Environment" attachment. Describe opportunities for intellectual interactions with other investigators, including journal clubs, seminars, and presentations.

11. Institutional Commitment to Candidate's Research Career Development

Who must complete the "Institutional Commitment to Candidate's Research Career Development" attachment:

The "Institutional Commitment to Candidate's Research Career Development" attachment is required.

Format:

Follow the page limits for the Institutional Commitment to Candidate's Research Career Development in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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

Content:

The sponsoring institution must provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the CDA. It is also essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

The "Institutional Commitment to Candidate's Research Career Development" attachment should generally document the institution's agreement to provide adequate time, support, equipment, facilities, and resources to the candidate for research and career development activities. See the list below for specific items to include in the document.

In the document describing its institutional commitment, the applicant organization must:

1. Agree to release the candidate from other duties and activities so that the candidate can devote the required percentage of time for development of a research career, as specified by the NOFO. For most K awards, commitment of at least 75 percent or nine person months of time is required.
    a. NIH and other PHS agencies use the concept of "person months" as a metric for determining percent of effort. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.
2. Describe actions that will be taken to ensure that the candidate can devote the required time to research career development (e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year). If the candidate's clinical or teaching responsibilities will be reduced, describe how this will be accommodated (e.g., hiring additional staff, reassigning staff, etc.).
3. Describe the candidate's academic appointment, bearing in mind that the appointment must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award.
4. Describe the proportion of time currently available for the candidate's research and what the candidate's institutional responsibilities will be if an award is made.
5. Describe how the institution will provide the candidate with appropriate office and laboratory space, equipment, and other resources (including access to clinical and/or other research populations) to carry out the proposed Research Plan.
6. Describe how the institution will be supportive of any proposed mentor(s), other staff, and/or collaborations with other faculty consistent with the career development plan.

Signatures:

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

name and title at the end of the statement. If the candidate will be working outside of the applicant institution (i.e., sponsoring institution), signatures from both the applicant/sponsoring institution and host institutions are required.

The sponsoring institution, through the submission of the application and in the institutional commitment section, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies.

Note: For applicable assurances, see the NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates.

12. Description of Candidate's Contribution to Program Goals

Who must complete the "Description of Candidate's Contribution to Program Goals" attachment:

Applicants to diversity-related NOFOs (e.g., diversity-related K01, K22s and K99s): The "Description of Candidate's Contribution to Program Goals" attachment is required.

All other Career Development applicants: Skip the "Description of Candidate's Contribution to Program Goals" attachment, as it is not required.

Format:

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

Content:

The sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the career development program to promote diversity in health-related research. The letter should avoid revealing sensitive personally identifiable information, such as the candidate's specific racial/ethnic background or type of disability.

For NIH's Interest in Diversity, see the Notice of NIH's Interest in Diversity (NOT-OD-20-031).

Signatures:

The "Description of Candidate's Contribution to Program Goals" attachment must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement.

Other Research Plan Sections

13. Vertebrate Animals

Who must complete the "Vertebrate Animals" attachment:

Include the "Vertebrate Animals" attachment if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the M.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: Animal Welfare Requirements (an applicable Animal Welfare Assurance will be required if the recipient institution does not have one)

14. Select Agent Research

Who must complete the "Select Agent Research" attachment:

Include the "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 your 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" section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions 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. Consortium/Contractual Arrangements

Who must complete the "Consortium/Contractual Arrangements" attachment:

Include the "Consortium/Contractual Arrangements" attachment if you have consortium/contracts in your budget.

Format:

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

Content:

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities

represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the recipient.

Note: The signature of the authorized organization representative in M.200 – SF 424 (R&R), Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

> *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.*

For more information:

Refer to the NIH Grants Policy Statement, Section 15: Consortium Agreements for more information.

Additional Instructions for Multi-project:

Overall and Other Components: Unless otherwise specified in the NOFO, you have the option to:

- include a single consolidated "Consortium/Contractual Arrangements" attachment in the Overall Component, or
- include component-specific "Consortium/Contractual Arrangements" attachment (s) within the components that include subawards, or
- include a "Consortium/Contractual Arrangements" attachment in the Overall Component and include component-specific attachments within the components that include subawards. Each filename must be unique.

16. Resource Sharing

Note: Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan.

Format:

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

Content:

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.

Research Tools: 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. For more information, see the Research Tools Policy on the NIH Scientific Data Sharing Website and the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

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 the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

17. Other Plan(s)

Who Must Complete This Section: Refer to the list of NIH activity codes subject to the DMS Policy and your NOFO to determine if your application is required to provide an attachment and address a Data Management and Sharing (DMS) Plan. Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan. Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.

The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan.

Applicants subject to both the NIH Data Management and Sharing Policy and the NIH Genomic Data Sharing Policy must attach a single Plan including elements for both policies. For more on applicability of each policy, see research subject to the NIH Data Management and Sharing Policy and the research subject to the NIH Genomic Data Sharing Policy.

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

A sample format is provided on the Data Management and Sharing Plan Format Page to assist applicants with preparation of this attachment. Do not include hyperlinks in this attachment. Recommended not to exceed two pages.

Content: Follow the expectations of the NIH Policy for Data Management and Sharing and address the Elements of an NIH Data Management and Sharing Plan described below.

Additional expectations: A Data Management and Sharing Plan should reflect the proposed approach at the time the application is prepared. For some programs and data types, NIH and/or NIH Institutes, Centers, Offices, or programs have developed additional data sharing requirements (e.g., specifying which scientific data to share, relevant standards, repository selection, timelines) that apply and should be reflected in a Plan. These additional requirements may be listed on NIH Institute and Center Data Sharing Policies or in specific Notice of Funding Opportunities. Note that some NIH Institutes, Centers, Officers, or programs have developed additional expectations for sharing genomic data that may be listed on NIH Institute and Center Genomic Data Sharing Expectations or in specific Notice of Funding Opportunities.

Elements of a Data Management and Sharing Plan:

Data Type: Briefly describe the scientific data to be managed, preserved, and shared, including a general summary of the types and estimated amount of scientific data to be

generated and a description of which scientific data from the project will be preserved and shared as well as the rationale for doing so. Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Related Tools, Software and/or Code: State whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software. If specialized tools or software are needed, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Standards: State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources (e.g., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation), and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Data Preservation, Access, and Associated Timelines: Provide plans and timelines for data preservation and access, including the name of the repository(ies) where scientific data and metadata arising from the project will be archived (do not include hyperlinks); how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools; and when (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) the scientific data will be made available to other users (e.g., the larger research community, institutions, and/or the broader public) and for how long. See Selecting a Data Repository on the NIH Scientific Data Sharing website.

Access, Distribution, or Reuse Considerations: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research, consistent with privacy, security, informed consent, and proprietary issues. Describe and justify any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements, or any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data. State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

Genomic Data Sharing Policy: For proposed research subject to the GDS Policy, state whether data, including genomic summary results, will be made available through controlled or unrestricted access; see instructions for describing Genomic Summary Results in Data Management and Sharing Plans.

If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures). See NIH's Scientific Data Sharing page for additional information on protecting human research participant privacy when sharing data.

Genomic Data Sharing Policy: For proposed research generating human genomic data within the scope of the GDS Policy, applicants should complete the Data Management and Sharing Plan anticipating sharing according to the assurances of the Institutional Certification.

If there is any element of the Institutional Certification that the institution (in consultation with the IRB) has determined cannot be met, please state which element and provide a

detailed explanation for why the element cannot be met. In such cases, the data management and sharing plan should describe how genomic data will be shared to the maximal extent possible (for example, sharing data in a summary format).

Oversight of Data Management and Sharing: Describe how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom at the applicant organization (e.g., titles, roles).

For more information on developing a Data Management and Sharing Plan, see Writing a Data Management and Sharing Plan on the NIH Scientific Data Sharing website.

For more information on the DMS Policy, including expectations for data management and sharing, protecting research participant privacy, and identifying data repositories, see the NIH Data Management and Sharing Policy on the NIH Scientific Data Sharing website and the NIH Grants Policy Statement, Section 8.2.3.1: Data Sharing Policy. **See also Frequently Asked Questions for additional information on the DMS Policy on these and other topics.**

For more information on the GDS Policy see the NIH Genomic Data Sharing Policy on the NIH Scientific Data Sharing website and the NIH Grants Policy Statement, Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)

Additional Instructions for Multi-project:

Overall Component Include a single consolidated "Data Management and Sharing Plan" in the Overall Component.

Other Components: Do not include a "Data Management and Sharing Plan" within other components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment in the Overall Component.

18. Authentication of Key Biological and/or Chemical Resources

Format:

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

Content:

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

More information:

Key biological and/or chemical resources are characterized as follows:

- Key biological and/or chemical resources may or may not have been generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
- See NIH's page on Rigor and Reproducibility for more information.

Appendix

19. Appendix

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

Additional Instructions for Multi-project:

Overall and Other Components: The "Appendix" attachment is optional.

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 filenames 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 NOFO 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 NOFOs may have different instructions for the Appendix. Always follow the instructions in your NOFO 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 NOFO.

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 NOFO. For example, do not include material transfer agreements (MTA) in the appendix unless otherwise specified in the NOFO.

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

Citizenship

Information on Citizenship Requirements for CDA Applicants:

The candidate must be a citizen or non-citizen national of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of award EXCEPT if any of the following apply:

- candidate is applying to the K99/R00 award program;
- candidate is applying to the K43 award program; or
- the NOFO specifies otherwise.

Note for permanent residents: Before an award is issued, a permanent resident will be required to submit a notarized statement that the candidate holds a current and valid Permanent Resident Card or some other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. as a permanent resident.

Note for candidates whose citizenship status changes or is expected to change: For those career development award programs that require candidates to be U.S. citizens or permanent residents, an individual who has applied for permanent residence and expects to have obtained such status prior to the time award may submit an application recognizing that no award will be made until legal verification of permanent resident status is provided. If a candidate's citizenship status changes after submission of the application, the new status should be reported in the candidate's Personal Profile in the eRA Commons.

Note on K99/R00 applicants on temporary visas: It is the responsibility of the applicant organization to determine and document in the application that the candidate's visa will allow him or her to remain in the U.S. long enough to complete the phase of the award (e.g., K99 or R00) covered by the application. Information may be requested by the NIH or another PHS Agency prior to issuance of an award as a Just-in-Time submission.

Check the applicable boxes for the following questions:

20. U.S. Citizen or Non-Citizen National?

Check "Yes" if the candidate is either a U.S. Citizen or a 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 possessions of the United States (e.g., American Samoa and Swains Island).

If no, select most appropriate Non-U.S. Citizen option:

Please select the most appropriate response from the options provided.

With a Permanent U.S. Resident Visa:

Check this box if the candidate 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 as part of the pre-award process.

With a Temporary U.S. Visa:

Check this box if the candidate currently holds a temporary U.S visa. This box is applicable only to specific programs that do not require U.S. citizenship or permanent residency (e.g., K99/R00).

Not Residing in the U.S.:

Check this box if the candidate is a citizen of a country other than the U.S. and plans to pursue career development outside of the U.S. This box is applicable only to specific programs (e.g., K43).

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:

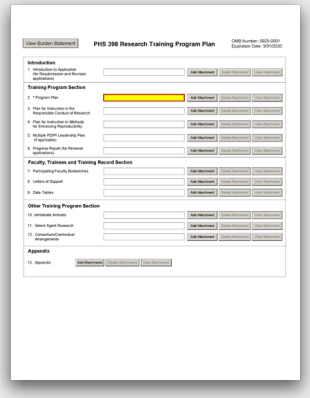
Check this box to indicate that permanent resident status is pending (i.e., if the candidate is not a U.S citizen but has applied for permanent residence and expects to hold a permanent resident visa by the earliest possible start date of the award). A notarized statement will be required as a part of the pre-award process. The statement must show that a licensed notary has seen the career development 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.

M.420 - PHS 398 Research Training Program Plan Form

The PHS 398 Research Training Program Plan Form is used only for Training applications and Multi-project applications with an "NRSA Training" Component.

This form includes fields to upload several attachments including the Program Plan, Faculty Biosketches, and Data Tables.

The attachments in this form, together with the rest of your application, should include sufficient information needed for evaluation of the training plan, independent of any other documents (e.g., previous application). Be specific and informative, and avoid redundancies.



View larger image

Quick Links

15. Appendix

Who should use the PHS 398 Research Training Program Plan Form:

Use the PHS 398 Research Training Program Plan Form only if you are submitting a training application or a multi-project application that has an "NRSA Training" Component.

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

Note on required tables: The instructions for the required Data Tables (1-8) are located on the NIH's Data Tables page. Please read the "Introduction to Data Tables" before beginning to prepare your data tables. The Introduction to Data Tables includes important definitions that should be used consistently both in the "Data Tables" attachment of your application and in all other parts of the application. The Data Tables must be included in the "Data Tables" attachment to avoid being counted against the page limits of other attachments.

Note on non-required tables: Additional tables (i.e., those that are generated by the applicant or not required by the NOFO) should be identified by letter, rather than number, to avoid confusion with the sequentially numbered required tables.

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 and Revision applications)

Who must complete the "Introduction to Application" attachment:

An "Introduction to Application" attachment is required only if the type of application is resubmission or revision or if the NOFO 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 NOFO. Note that page limits for the Introduction may differ based on the type of application (i.e., resubmission or revision).

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.

Note: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the introduction.

Competing Revision Applications: See specific instructions on the content of the Introduction on the NIH's Competing Revisions page.

Additional Instructions for Multi-project:

Other Components: The "Introduction" attachment is optional for resubmissions and revisions applications. Although the "Introduction" attachment is optional, you may get a system warning if there is no attachment.

Training Program Section

2. Program Plan

Who must complete the "Program Plan" attachment:

The "Program Plan" attachment is required.

Format:

Follow the page limits for the Program Plan in the NIH Table of Page Limits unless otherwise specified in the NOFO. The Program Plan (including sections "A. Background;" and "B. Program Plan;") must fit within the Program Plan page limit unless otherwise specified in the NOFO.

Note that Data Tables may be referred to or summarized in this section; however, the actual tables are not to be included in this attachment.

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

Content:

Organize the Program Plan attachment in the specified order and use the instructions provided below unless otherwise specified in the NOFO. Start each section with the appropriate heading – Background or Program Plan. In addition, start each subsection of the Program Plan with the appropriate subheading.

Check the NOFO and the instructions for the Data Tables to determine which tables should be included in the application and discussed in the Program Plan subsection.

A. Background

Provide the rationale for the proposed research training program, the relevant background history, and the need for the proposed research training. Describe the training program goals and objectives related to the program rationale.

Indicate how the proposed program relates to current training activities at the applicant organization.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program.

If required, complete Tables 1-3 (these tables will be included in the Data Tables attachment), and summarize the data here using the guidance below. In your narrative, refer to specific tables as applicable.

Table 1. Census of Participating Departments and Interdepartmental Programs: Describe the organization of the proposed training program, the participating departments and interdepartmental programs, and the extent to which faculty, graduate students, and/or postdoctorates from those departments/interdepartmental programs participate in the programmatic activities to be supported by the training grant.

Table 2. Participating Faculty Members: Describe the distribution of participating faculty by academic rank, department or interdepartmental program and areas of research emphasis. Describe the rationale for the faculty selected to participate in the training grant. Analyze the data in terms of the overall experience of the faculty in training predoctorates and/or postdoctorates. Comment on the inclusion of faculty whose mentoring records may suggest limited, recent training experience at either training level (predoctoral or postdoctoral).

Table 3. Federal Organizational Research Training Grant and Related Support Available to Participating Faculty Members: Summarize the level of research training support at the organization. Comment on instances where the tabular data indicate that there may be substantial overlap of participating faculty.

B. Program Plan

Note: Applicants for institutional career development awards (e.g., K12) must complete a Research Career Development Program Plan instead of the Training Program Plan. Refer to specific instructions in the NOFO.

a. Program Administration *(Training Program Director(s)/Principal Investigator(s))*

Program Director information: Describe the program director's qualifications for providing leadership of the program, including relevant scientific background, current research areas, experience in research training and commitment to training future researchers. Indicate the program director's percent effort in the proposed program. Describe how the PD(s)/PI(s) will receive training on effective mentoring practices to promote trainee success and foster an inclusive, safe, and supportive research training environment.

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

> **Special Instructions for Multiple PD/PI:** If multiple PD/PIs are proposed, explain in this section your rationale for how this will facilitate program administration. In addition, you must complete the Multiple PD/PI Leadership Plan attachment in this form.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the program plan and include the required Multiple PD/PI

Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the program plan.

b. Program Faculty

Referring to the data presented in Table 2. Participating Faculty Members, describe each faculty member's research that is relevant to the program and indicate how trainees will participate in the research. Provide information on the extent to which participating faculty members have cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research. In programs where trainees will have multiple mentors, describe how the training faculty will effectively coordinate communication, training, and mentorship responsibilities.

Use this section to document the ability of the faculty to support the research activities of the proposed trainees, the training experience of the participating faculty members, the success of their trainees in generating publishable research results, and how previous mentoring experience will support their role in the proposed training program (for early career faculty participating in the program, mentoring experience from their time as a postdoctoral scientist or in a non-faculty position can be included)

Describe planned mentor training activities for the participating faculty to ensure the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds. For any proposed participating faculty (i.e., program faculty) members lacking research training experience, describe a plan to ensure that they will successfully guide trainees. Describe the criteria used to appoint and remove faculty as program faculty and to evaluate their participation.

If required, complete Tables 4-5 (these Tables will be included in the Data Tables attachment), and summarize the data here using the guidance below. In your narrative, refer to specific tables, as applicable.

Table 4. Active Research Support of Participating Faculty Members: Analyze the data in terms of total and average grant support. Additionally, comment on the inclusion of faculty without research grant support and explain how the research of trainees who may work with these faculty members would be supported.

Table 5. Publications of Trainees Supported by this Program: Summarize these data, including, for example, the average number of publications, and how many students have published their work. For pre- and postdoctoral training programs, indicate how many trainees are published as first author, and how many completed their doctoral or postdoctoral training without any first-author publication.

Note for New Applications: List publications for students and/or postdoctorates who are representative of those who would be appointed if the grant is awarded.

c. Proposed Training

Describe the proposed training program. Indicate the training level(s) and number of trainees, the academic and research background needed to pursue the proposed training, and, as appropriate, plans to accommodate differences in preparation among trainees. For postdoctoral trainees, indicate the proposed distribution by degree (e.g., M.D., Ph.D.). Describe course work, research opportunities and the extent to which trainees will participate directly in research, activities designed to develop technical and/or professional skills, and the duration of training, i.e., usual period of time required to complete the training offered.

For programs that propose short-term training, any didactic training must be well structured and appropriately justified for the duration of the training experience. Short-term trainees must have the opportunity to carry out supervised biomedical, behavioral, or clinical research with the primary objective of developing or enhancing their research skills and knowledge in preparation for a health-related research career.

For renewal applications, highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational and mentoring practices, and to evaluation of the training program.

Describe how the program and faculty will provide training in scientific reasoning, rigorous research design, relevant experimental methods, relevant quantitative and data science approaches, and data analysis and interpretation, appropriate to the level and prior preparation of the trainees.

For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated and how they will relate to an individual trainee's experience.

Describe career development activities for trainees involved in the program. Include discussion of how trainees will be provided with information about the careers in the biomedical research workforce for which their training may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers. Describe involvement of relevant program faculty and staff in activities to promote trainee career progression.

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

Training programs that anticipate offering trainees opportunities to be involved in human subjects research funded by other research grants may include a brief description of those opportunities in this section, although such a description is not required.

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

d. Training Program Evaluation

Describe an evaluation plan to review and determine the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the training program and to provide suggestions for program improvements, as well as plans to respond to appropriate feedback. Specified evaluation metrics should be tied to the goals of the program. In addition, describe plans for assessing the career development and progression of trainees, including publications, degree completion, and post-training positions.

Renewal Applications: Discuss evaluation results and indicate whether the program has been modified as a result.

e. Trainee Candidates and Retention Plans

Describe, in general terms, the size of the training program candidate pool, including information about the types of prior clinical and research training and the career level. Describe specific plans to recruit candidates and explain how these plans will be implemented (plans may expand upon but should not duplicate those found in the "Recruitment Plan to Enhance Diversity" attachment). Describe the nomination and selection process to be used to select candidates who will be offered admission to the program and criteria for trainees' reappointment to the program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program. Note: While program admissions processes can consider a variety of factors – such as how a trainee candidate's experiences and perspectives further their commitment to program goals and a career in the biomedical research workforce - programs may not use the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of a trainee or candidate as an eligibility or selection criteria.

Describe trainee retention plans (that is, activities designed to sustain the scientific interests and participation of trainees from all backgrounds in the program).

If required, complete Tables 6A and/or 6B (these Tables will be included in the Data Tables attachment), and summarize the data here using the guidance below. In your narrative, refer to specific tables as applicable.

> **Table 6. Training Program Candidates, Entrants, and their Characteristics for the Past Five Years (Predoctoral and Postdoctoral)**. Summarize the data in terms of the overall numbers of potential trainees, their characteristics, their eligibility for support, and enrollment trends.

f. Institutional Environment and Commitment to Training

Include information in the application that documents the support and commitment of the applicant organization and participating units and departments to the goals of the proposed program. This could include, for example, space, shared laboratory facilities and equipment, funds for curriculum development, release time for the PD/PI and participating faculty, support for additional trainees in the program, or any other creative ways to improve the environment for the establishment and growth of the research training program.

Include a signed letter, on institutional letterhead, that describes the applicant organization's commitment to the planned program (see instructions in the Letters of Support section). Institutions with ongoing research training, student development, or career development programs that receive external funding should explain what distinguishes the proposed program from existing ones at the same trainee level; how the programs will synergize, if applicable; whether trainees are expected to transition from one support program to another; and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

g. Training Outcomes

Describe the ability of the participating departments/programs to recruit potential trainees and retain trainees through the completion of their training, the results of the admissions process (e.g., how many offers and matriculants), and the experience of the departments/programs in recruiting potential trainees from diverse backgrounds (see "Recruitment Plan to Enhance Diversity" attachment.

Discuss the of the applicant pools, including both training-grant eligible and non-training-grant eligible individuals and the characteristics of current program participants, referring to the data in Table 6, as applicable.

Use all of this information to justify the number of positions requested.

If required, complete Tables 7-8 (these Tables will be included in the Data Tables attachment) and summarize the data using the guidance below. In your narrative, refer to specific tables as applicable.

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Table 7. Appointments to the Training Grant for Each Year of the Current Project Period: Describe the utilization of awarded training positions. If any trainee positions were not filled, if any trainees terminated early, or if the distribution of appointed positions differs from the distribution of awarded positions, provide an explanation.

Table 8. Program Outcomes: Referring to relevant components of Table 8, describe how training positions are used (i.e., distribution by mentor, year in program, years of support per trainee), and the success of the program in achieving its training goals and objectives. For those who have completed their training, describe the extent of their current involvement in research, including research grant support received subsequent to completion of the training program.

Renewal applications: Discuss the appointments to the training grant, and if any postdoctoral trainee with a health professional degree was appointed to a Kirschstein-NRSA training grant for less than 2 years of research training, explain why.

3. Recruitment Plan to Enhance Diversity

Who must complete the "Recruitment Plan to Enhance Diversity:"

A Recruitment Plan to Enhance Diversity is required for all training grant activity codes **except** T34, T36, U2R, and all D-series activity codes. All other applications without a Recruitment Plan to Enhance Diversity will be considered incomplete and will not be reviewed.

Content:

Scope

For purposes of this requirement, "recruitment" means outreach efforts intended to encourage individuals to apply for the training grant program. These are efforts that occur prior to the candidate review and selection process. "Recruitment" does not mean the appointment or hiring of an individual into the training grant program.

History and Achievements

Describe efforts to diversify the program applicant pool by recruiting potential trainees from underrepresented groups, for example, underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds, for the existing training program. Refer to the Notice of NIH's Interest in Diversity for examples of groups underrepresented in the biomedical research enterprise.

Proposed Plans

Describe steps to be taken during the proposed award period to identify and recruit potential training program candidates from underrepresented groups, for example individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds (see Notice of NIH's Interest in Diversity) Additionally, literature shows that women from these backgrounds face particular challenges at the graduate level and beyond in scientific fields. Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school, and/or the university at large. In most cases, centralized institutional efforts alone will not satisfy the requirement to recruit potential trainees from underrepresented groups, and training grant faculty are expected to be actively involved in recruitment efforts.

New Applications: Include a description of plans to enhance recruitment, including the strategies that will be used to enhance the recruitment of potential trainees from underrepresented groups.

Renewal Applications: Include an account of experiences in recruiting potential trainees from underrepresented groups during the previous funding period, including successful and unsuccessful recruitment strategies. Information should be included on how the proposed plan reflects the program's past experiences in recruiting individuals from underrepresented groups.

For more information:

Refer to the Notice of NIH's Interest in Diversity.

4. Plan for Instruction in the Responsible Conduct of Research

Who must complete the "Plan for Instruction in the Responsible Conduct of Research" attachment:

A "Plan for Instruction in the Responsible Conduct of Research (RCR)" attachment is required for all training grant activity codes except T36, unless otherwise noted in the NOFO. Applications lacking a Plan for Instruction in RCR will not be reviewed.

Format:

Follow the page limits for the Plan for Instruction in the Responsible Conduct of Research in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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 RCR, as more fully described in the NIH Grants Policy Statement, Section 11.3.3.5: Training in the Responsible Conduct of Research:

1. **Format:** Describe the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups. A plan with only on-line instruction is not acceptable.
2. **Subject Matter:** Describe the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics.

3. **Faculty Participation:** Describe the roles of mentor(s) and other faculty involvement in the instruction.
4. **Duration of Instruction:** Describe the total number of contact hours of instruction.
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.

The plan must also describe how participation in RCR instruction will be monitored.

Renewal Applications: Describe any changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current RCR instruction. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

For more information:

See the NIH Grants Policy Statement, Section 11.3.3.5: Training in the Responsible Conduct of Research.

5. Plan for Instruction in Methods for Enhancing Reproducibility

Who must complete the "Plan for Instruction in Methods for Enhancing Reproducibility" attachment:

A "Plan for Instruction in Methods for Enhancing Reproducibility" attachment is required for all training grant activity codes except D71, unless otherwise noted in the NOFO. Applications lacking a Plan for Instruction in Methods for Enhancing Reproducibility will not be reviewed.

Format:

Follow the page limits for the Plan for Instruction in Methods for Enhancing Reproducibility in the NIH Table of Page Limits unless otherwise specified in the NOFO.

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

Content:

The plan must describe how trainees will be instructed in principles important for enhancing research reproducibility. These principles include, at a minimum, the following:

- evaluation of the foundational research underlying a project (i.e., the rigor of the prior research);
- rigorous experimental design and data interpretation;
- consideration of relevant biological variables such as sex;
- authentication of key biological and/or chemical resources; and
- transparency in reporting.

Include a description of how instructional strategies will be integrated into the overall training program at multiple stages of trainee development and in a variety of formats and contexts. Describe how program faculty will reiterate and augment key elements of methods for enhancing reproducibility in the context of trainees' research projects.

Renewal Applications: Describe any changes in instruction over the past project period and plans that address any weaknesses in the current instruction for methods for enhancing reproducibility.

6. Multiple PD/PI Leadership Plan (if applicable)

Who must complete the "Multiple PD/PI Leadership Plan" attachment:

Any applicant who designates multiple PD/PIs (on the M.240 - R&R Senior/Key Person Profile (Expanded) Form) must include a Multiple PD/PI Leadership Plan. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the M.240 - R&R Senior/Key Profile (Expanded) Form, even those at organizations other than the applicant organization.

Do not submit a leadership plan if you are not submitting a multiple PD/PI application.

Additional Instructions for Multi-project:

Overall Component: The "Multiple PD/PI Leadership Plan" attachment is required only in the Overall Component.

Format:

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

Content:

The emphasis in a training grant's Multiple PD/PI Leadership Plan should be on how multiple PD/PIs will benefit the program and the trainees. A single PD/PI must be designated as Contact PD/PI (in M.200 - SF 424 (R&R) Form, PD/PI Contact Information) for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD/PI when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PD/PIs. A single award will be made. Multiple PD/PI plans should include reasonable numbers of PD/PIs and each should be included for a specific and clearly stated purpose.

A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the training program should be described, including communication plans, processes for making decisions, and procedures for resolving conflicts. The roles and administrative, technical, and other responsibilities for the training program should be delineated for the PD/PIs and other collaborators.

Resubmission Applications: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the program plan and include the required Multiple PD/PI Leadership Plan.

For more information:

For background information on the multiple-PD/PI initiative, see NIH's Multiple Principal Investigators page.

7. Progress Report (for Renewal applications)

Who must complete the "Progress Report" attachment:

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

Format:

Follow the page limits given below, unless otherwise specified in the NOFO.

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

Content:

Organize the Progress Report according to the specified sections. Start each section with the appropriate heading – Program Overview or Progress of Those Appointed to the Grant.

Program Overview (Page limit: 5 pages)

Provide an overview of accomplishments and progress achieved in the period since the last competitive review. Focus on elements specific to the training program (rather than on opportunities generally available in the institution's other departments or other programs).

If training goals from the previous period were not met, provide explanations and explain alternative approaches taken to address them.

Describe how the funds provided under Training Related Expenses were used to benefit the program.

List any workshops or seminars sponsored by the program. Include the workshop/seminar titles, speakers, and relevance to the theme and training objectives of the program.

Indicate whether the training program uses Individual Development Plans (IDPs). If so, describe how IDPs were used in this reporting period to help manage the trainees'/scholars' training and career development.

Note: Do not include actual IDPs or blank IDP forms.

Note for AHRQ trainees: Neither IDPs nor information about IDPs is required.

You may refer to information that is included elsewhere in the application, such as the Program Plan or outcomes described in the Training Data Tables, but do not repeat that information in the Progress Report.

Progress of Those Appointed to the Grant (Page limit: 1 page per appointee)

For each trainee or scholar appointed to the grant in the period covered since the last competitive review, provide a summary of his or her training and progress, including the following information, as applicable:

- Degrees working toward or received;
- Mentor(s);
- Description of the trainee/scholar's research project and progress;
- Career development activities (e.g., individualized coursework or workshops attended);
- Conference presentations;
- A description of the trainee's contribution to any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment, analyzed data, drafted paper); and

- Honors, awards, fellowships, and any other support received during the period of training. **Note:** Support before and after the appointment is reported in the Data Tables and should not be reported here.

Do not include the following, either in the Progress Report or elsewhere in the application (including the Appendix), unless otherwise specified in the NOFO:

- Biosketches of current or former trainees/scholars;
- Any sensitive personally identifiable information, such as photographs or any other individual demographic information;
- Actual IDPs or blank IDP forms;
- Promotional material for workshops, seminars, or other events (flyers, agendas, etc.);
- Course syllabi; and
- Program brochures.

Applications that include any of these materials will be withdrawn and not reviewed.

Note: A My Bibliography report of publications arising from work conducted by trainees while supported by the training grant is not required in the application. However, it will be collected in the Interim Final Research Performance Progress Report.

Additional Instructions for Multi-project:

Overall and Other Components: If you include a "Progress Report Publication List" attachment, you can include it in either the Overall Component or within the Other Component, but do not attach the same information in multiple locations.

Faculty, Trainees And Training Record Section

8. Participating Faculty Biosketches

Format:

Combine all participating faculty biosketches into a single PDF and attach this information here. Follow the attachment guidelines on NIH's Format Attachments page.

Content:

Faculty biosketches for participating faculty must follow the instructions for a biographical sketch (refer to M.240 - Senior/Key Person Profile (Expanded) Form) with the following exception: a personal statement, while encouraged, is not required.

Please note that the biosketches of the PD/PI and any other senior/key personnel (e.g., co-directors, if applicable, and program staff) should not be included here, but they should instead be included in the M.240 - R&R Senior/Key Person Profile (Expanded) Form.

9. Letters of Support

Format:

Combine all Letters of Support into a single PDF file and attach this information here. Do not place these letters in the Appendix. Follow the attachment guidelines on NIH's Format Attachments page. Use of hyperlinks and URLs in Letters of Support is not allowed unless specified in the Notice of funding opportunity.

Content:

Attach letters here from:

- Consultants, if applicable. Letters should include rate/charge for consulting services and confirm their role(s) in the project.
- Senior Administration Officials. This letter should be a signed letter on institutional letterhead, and it should describe the applicant institution's commitment to the planned program.

- A President, Provost, Dean, Department Chair, or other key institutional leader with institution-wide responsibilities. This letter should be a signed letter on institutional letterhead, and it should describe and acknowledge institutional commitment to the following areas:
  - Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices;
  - Responding appropriately to allegations of discriminatory practices, including any required notifications to the HHS Office of Civil Rights; and
  - Adopting and following institutional procedure for requesting NIH prior approval of a change in the status of the Program Director/Principal Investigator (PD/PI) or other senior/key personnel if administrative or disciplinary action is taken that impacts the ability of the PD/PI or other key personnel to continue his/her role on the NIH award as described in the training grant application.

Check the NOFO (particularly for non-NRSA programs) to determine whether any additional program-specific letters of support are required.

For more information:

Notice of Clarification Regarding Harassment and Discrimination Protections in NIH Training Applications

NIH Grants Policy Statement, Section 4.1.2: Civil Rights Protections

NIH Grants Policy Statement, Section 8.1.2.6: Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NOA.

10. Data Tables

Format:

The information provided in the required data tables (Data Tables 1-8 described below) will not be counted toward the page limitation. These tables should be numbered consecutively and titled as instructed. Start each numbered table on a new page.

Bookmark each table separately in the PDF attachment. Many PDF generators will automatically create bookmarks from text formatted using predefined Heading styles in Word.

Combine all Data Tables into a single PDF file and attach it here. See NIH's Format Attachments page.

Content:

Instructions for Data Tables 1-8 are located on NIH's Data Tables page. These instructions include an Introduction to the Data Tables that provides instructions applicable to all tables, specific instructions for each table, and Sample Data Tables. The sample data tables illustrate the kind of data to include in each table for training grant applications.

If not using the Extramural Trainee Reporting and Career Tracking (xTRACT) system to prepare data tables, be sure to choose the Instruction and Blank Data Table set that correspond to both the type of application you are submitting (e.g., new application, renewal or revision application) and the kind of training to be provided (e.g., predoctoral only, postdoctoral only, pre and postdoctoral mixed, etc.).

Other Training Program Section

11. 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 M.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 Program Plan.

Content:

Trainee Participation Only in Research Involving Vertebrate Animals that is Part of Other Research Project Grants: Describe how the institution will ensure that trainees participate only in IACUC-approved vertebrate animal research if the following two conditions apply:

- the training program uses live vertebrate animals only as part of other research project grants, and
- the training grant does not support the purchase, use, or husbandry of live vertebrate animals.

Independent Trainee Research Involving Vertebrate Animals: In training programs where trainees will design and conduct their own independent vertebrate animal research, follow the instructions below:

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 "Program Plan" 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 three 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: Animal Welfare Requirement (an applicable Animal Welfare Assurance will be required if the recipient organization does not have one)

12. Select Agent Research

Who must complete the "Select Agent Research" attachment:

Include a "Select Agent Research" attachment if the proposed training activities will 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 of 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:

If participating faculty proposed in the training program are conducting or plan to conduct research involving select agents in which trainees may participate, follow the instructions below.

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, 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 organization, 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.

13. Consortium / Contractual Arrangements

Who must complete the "Consortium/Contractual Arrangements" attachment:

Include the "Consortium/Contractual Arrangement" attachment if you have consortiums/contracts in your budget.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs is not allowed in this section unless specified by the funding opportunity.

Content:

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the recipient.

Note: The signature of the authorized organization representative on the M.200 - SF 424 (R&R) Form, Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

For more information:

Refer to the NIH Grants Policy Statement, Section 15: Consortium Agreements for more information.

14. Other Plan(s)

For NIH Training Grant Applicants, the Data Management and Sharing (DMS) Plan is not required.

For more information on the DMS Policy see the NIH Data Management and Sharing Policy on the NIH Scientific Data Sharing website or the NIH Grants Policy Statement, Section 8.2.3.1: Data Sharing Policy. See also Frequently Asked Questions for additional information on the DMS Policy on these and other topics.

Additional Instructions for Multi-project:

Overall Component: Include a single consolidated "Data Management and Sharing Plan" in the Overall Component.

Other Components: Do not include a "Data Management and Sharing Plan" within other components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment in the Overall Component.

Appendix

15. Appendix

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

Additional Instructions for Multi-project:

Overall and Other Components: The "Appendix" attachment is optional.

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Use of hyperlinks and URLs is not allowed unless specified by the funding opportunity.

As a reminder, tables *other* than the required Data Tables 1-8 must be incorporated into the Program Plan (and will count toward the Program Plan's page limits), and must not be included in the Appendix. Follow the page limits for Institutional Training Grants specified in the NIH Table of Page Limits, unless otherwise specified in the NOFO.

Use filenames 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 NOFO 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 NOFOs may have different instructions for the Appendix. Always follow the instructions in your NOFO if they conflict with these instructions

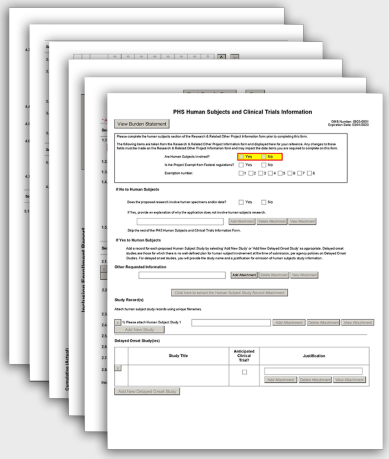
Note: Applications will be withdrawn and not reviewed if they do not follow the appendix requirements in these instructions or in your NOFO.

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 NOFO. For example, do not include material transfer agreements (MTA) in the Appendix unless otherwise specified in the NOFO.

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

M.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 Notice of Funding Opportunity (NOFO) before completing this form to ensure your application meets all IC-specific criteria. "Section II. Award Information" of the NOFO will indicate whether clinical trials are or are not allowed and whether clinical trial research experience is or is not allowed. The designation of your NOFO will determine how to use these instructions, and subsequently, how to fill out this form.

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

Complete the PHS Human Subjects and Clinical Trials Information form after you have completed the M.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:

The designation of your NOFO will determine how to use these instructions, and subsequently, how to fill out this 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 M.220 - R&R Other Project Information Form.

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:

Everyone must complete the "Use of Human Specimens and/or Data" section of the PHS Human Subjects and Clinical Trials Information form. However, your answer to the "Are human subjects involved?" question will determine which other sections of the PHS Human Subjects and Clinical Trials Information form you must complete. Once you have completed the "Use of Human Specimens and/or Data" section, follow instructions on the form that are specific to your answer to the "Are human subjects involved?" question on the M.220 - R&R Other Project Information Form:

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

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, you will add detailed information at the study level. 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.

For more information on what a "study" is for the purposes of the PHS Human Subjects and Clinical Trials Information form, see the relevant FAQ on the Applying Electronically FAQ page.

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.

Note: Some fields in this form match fields within ClinicalTrials.gov and are identified as such within these instructions. Additional information about the fields can be found on the ClinicalTrials.gov Protocol Registration Data Element Definitions website.

Additional Instructions for Multi-project:

For multi-project applications with studies that are self-contained within a single component:

Overall Component: Do not complete a Study Record.

Other Component: Complete a separate Study Record for each human subjects study that is self-contained within a single component.

For multi-project applications with studies that span components:
Overall Component: Complete one Study Record for each study if it spans multiple components. This Study Record must include sufficient information for all components that are involved in the particular study. This might occur when an application includes a data coordinating center or recruitment core, or when participant assessments for one study are conducted across multiple components (e.g., the study includes an imaging core and clinical site).

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
- Rules for Text Fields
- 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
- NIH's Human Subjects Research website
- NIH's Clinical Trials website
- Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

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 M.220 - R&R Other Project Information Form prior to completing this form.

Use of Human Specimens and/or Data

Regardless of your answer to the question "Are Human Subjects Involved?" on the M.220 - R&R Other Project Information Form, answer the following question(s) about the use of human specimens and/or human data.

Does any of the proposed research in the application involve human specimens and/or data?

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

Note: 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.

Provide an explanation for any use of human specimens and / or data not considered to be human subjects research.

If you answered "No" to the "Does any of the proposed research in the application involve human specimens and/or data?" question, you do not need to attach an explanation here.

If you answered "Yes" to the "Does any of the proposed research in the application involve human specimens and/or data?" question, you must provide an explanation for any use of human specimens and/or data not considered to be human subjects research. To help determine whether your research is classified as human subjects research, refer to the Research Involving Private Information or Biological Specimens flowchart. Do not describe use of human specimens and / or data considered to be human subjects research here. For any human specimens and/or data that is considered human subjects research, you will add a Study Record. Do not duplicate the information in your explanation in any of your Study Records.

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

This explanation 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.

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

Are Human Subjects Involved? Yes/No

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

Is the Project Exempt from Federal regulations? Yes/No

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

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

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

Note: If you change your answer to the "Are Human Subjects Involved" question on the M.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 M.220 - R&R Other Project Information Form, skip the rest of the PHS Human Subjects Clinical Trials Information form unless otherwise directed by your NOFO.

If Yes to Human Subjects

If you answered "Yes" to the question "Are Human Subjects Involved?" on the M.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 NOFO 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. Hyperlinks and URLs are not allowed unless specified in the funding opportunity.

Content:

Content is limited to what is described in your NOFO 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).

Additional Instructions for Multi-project:

For multi-project applications with studies that span components:

Overall Component: For each study that spans components, describe the components involved with the study.

Other Components: Each component should include an attachment that indicates that the details of the study are included in the Overall component within this attachment.

For more information, see the "Where do I enter my human subjects study information in my multi-project application" FAQ on the Applying Electronically FAQ page.

Study Record(s)

Adding Study Record Attachment(s):

Add a study record for each proposed study involving human subjects. Projects involving public health surveillance activities described in 45 CFR 46.102(l)(2) must complete one or more Study Records describing those public health surveillance activities as if the exclusion does not apply. If specific plans for your study involving human subjects can be described in the application but will not begin immediately (i.e., your study has a delayed start), you must add a Study Record for that study. If your study anticipates involving human subjects within the period of award but specific plans cannot be described in the application (i.e., delayed onset), 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.

Note on Grouping Studies into Study Records: While there may be more than one way to split or group studies into Study Records, you are encouraged to group studies that use the same human subjects population and same research protocols into a single Study Record, to the extent that the information you provide is accurate and understandable to NIH staff and reviewers.

If information in any attachment is identical across studies, include the complete information only in the first Study Record for which the information is relevant. In the subsequent Study Records for which the identical information is needed, upload an attachment that says, "See information for attachment X in Study Record entitled [include study title]." No other information is needed in the attachment. Do not submit attachments that are duplicated from one Study Record to another. Note that you should not name Study Records by number. Examples of attachments that may be

identical across studies include, but are not limited to, the 3.1 Protection of Human Subjects and 3.5 Overall Structure of the Study Team attachments.

See the NIH Glossary definitions of Study and Study Record.

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

Format:

All attachments must be PDF files. If you extract a Study Record, it will already be in a fillable PDF format. Please use this PDF file and do not alter the format of the Study Record file. Use unique filenames for each human subject study record. The filename for each attachment within a study must be unique within the application (i.e., do not use the same filename in multiple Study Records). Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

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

Delayed Onset Study(ies)

If you anticipate conducting research involving human subjects but cannot describe the study at the time of application (i.e., your study is a delayed onset human subject study), enter a Delayed Onset Study Record as instructed below.

Generally, for any study that you include as a delayed onset study in this section, you will provide a study title, indicate whether the study is anticipated to include a clinical trial, and include a justification attachment. Since by definition, information for a delayed onset study is not available at the time of application, you will not be given the option to complete a full Study Record for a delayed onset study. For delayed onset studies, the Delayed Onset Study 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). Refer to the NIH Glossary definition of Delayed Onset Study and Delayed Start.
- If you anticipate multiple delayed onset studies, you can include them together in a single Delayed Onset Study Record.

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 NOFO 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.

Justification Attachment

This attachment is required.

Attach the justification as a PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

- 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 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.

Note: This field matches a ClinicalTrials.gov field (Official Title).

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 Definition of Human Subjects Research website.

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. Regardless of whether these exemptions may apply to you in the future, you must fill out your application following the instructions below.

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 Human Subjects FAQs.
- See the NIH's Human Subjects Exemption FAQs

The Office for 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. See NIH Grants Policy Statement Section 4.1.15 for more information.

1.4 Clinical Trial Questionnaire

The Clinical Trial Questionnaire is required.

Note for basic and mechanistic studies involving human participants: The NIH definition of a clinical trial encompasses a broad range of studies, including studies using human participants that aim to understand fundamental aspects of phenomena, the pathophysiology of a disease, or the mechanism of action of an intervention. This includes many mechanistic studies and studies submitted to Basic Experimental Studies with Humans NOFOs.

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.

Note: The answer to question "1.4.a Does the study involve human participants?" will be pre-populated with "Yes" for all study records. You will not be able to change this answer.

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
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 NOFO	Do not complete

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
- NIH Clinical Trial Definition FAQ
- 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. Enter the identifier only if you are proposing to work on that specific clinical trial. If you are only getting samples and/or data from a clinical trial that has already been entered into ClinicalTrials.gov, do NOT enter the identifier.

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

Note: The number you enter in this field should match the ClinicalTrials.gov identifier assigned by ClinicalTrials.gov.

Section 2 - Study Population Characteristics

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

All of "Section 2 – Study Population Characteristics" is required (see exceptions for Question 2.7 Study Timeline and for Question 2.8 Enrollment of First Subject) for all human subjects studies unless the following applies 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.

2.1 Conditions or Focus of Study

At least 1 entry is required, and up to 20 entries are allowed (enter each entry on its own line). 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.

Note: This field matches a ClinicalTrials.gov field (Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study).

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 (but typically needs only 500 characters).

Note: This field matches a ClinicalTrials.gov field (Eligibility Criteria).

For more information about formatting text entry fields, see NIH's Rules for Text Fields page and the ClinicalTrials.gov's Protocol Registration and Results System User's Guide.

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.

Note: This field matches a ClinicalTrials.gov field (Age Limits).

2.3.a Inclusion of Individuals Across the Lifespan

Format:

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

Content:

Discuss each of the points listed below. Also include any additional information requested in the NOFO.

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.

Inclusion of Individuals Across the Lifespan

For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section. In addition, address the following points:

- Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects for additional information about circumstances that may justify the exclusion of individuals based on age.
- Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will 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.

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 Inclusion - Basis of Sex/Gender and Race/Ethnicity.

For more information, see:

- NIH Policy Implementation Page on Inclusion Across the Lifespan
- Inclusion Across the Lifespan: Guidance for Applying the Policy infographic
- NIH FAQs on Inclusion Across the Lifespan
- HHS' 45 CFR 46 Subpart D – Additional Protections for Children
- NIH Grants Policy Statement, Section 4.1.15.7: Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

2.4 Inclusion of Women and Minorities

Format:

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

Content:

Discuss each of the points listed below and include any additional information requested in the NOFO.

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.

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 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 Inclusion - Basis of Sex/Gender and Race/Ethnicity..

NIH-Defined Phase III Clinical Trials. If the proposed research includes an NIH-Defined Phase III Clinical Trial, the "Inclusion of Women and Minorities" 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.

For more information, see:

- NIH's Inclusion of Women and Minorities as Participants in Research Involving Human Subjects
- HHS' 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Fetuses, and Neonates
- 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 the following applies to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" 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 the following applies to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.

Content:

From the dropdown menu, select the "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)

Note: This field matches a ClinicalTrials.gov field (Overall Recruitment Status).

2.7. Study Timeline

Who must complete the "Study Timeline" attachment:

The "Study Timeline" attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire" (i.e., your study is a clinical trial).

The "Study Timeline" attachment is optional if either of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.
- You answered "No" to any of the questions in the "Clinical Trial Questionnaire" (i.e., your study is not a clinical trial).

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 Participant

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

Do not complete this field if you will answer "Yes" to the question "Using an Existing Dataset or Resource" in the Inclusion Enrollment Report.

The "Enrollment of First Participant" question is otherwise required unless the following applies to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.

Content:

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

2.9. 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: 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 NOFO 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 NOFO.

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.

Additional Instructions for Multi-project:

For multi-project applications with studies that are self-contained within a single component:

Other Component: Include the IER(s) with the component(s) that involves the study (s), unless otherwise directed by the NOFO.

For multi-project applications with studies that span components:

Overall Component: Should the study span more than one component, include the IER with the Study Record in the Overall Component and insert a comment in the comment field of the IER to indicate what other components it is associated with.

For more information:

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

1. Inclusion Enrollment Report Title

The "Inclusion Enrollment Report Title" field is required.

The "Inclusion Enrollment Report title can have a maximum of 600 characters.

Enter a unique title for each IER. The title should indicate specific criteria that uniquely identify each report. If the Project Title is pre-populated, you may edit it so that each IER title is unique.

2. Using an Existing Dataset or Resource?

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

If the study involves analysis of an existing dataset or resource (e.g., biospecimens) only, answer "Yes" to this question. If the study involves prospective recruitment or new contact with participants answer "No" to this question. Use separate IERs for studies involving use of existing datasets or resources only and for studies that involve prospective recruitment or new contact with study participants.

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 ResourcesFAQs on Inclusion - Basis of Sex/Gender and Race/Ethnicity.

3. 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. 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 Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

4. Enrollment Country(ies)

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

Indicate the country or countries in which participants will be enrolled. 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.

5. 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.

6. 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.

Additional Instructions for Multi-project:

For multi-project applications with studies that span components:

Overall Component: Should the study span more than one component, include the IER with the Study Record in the Overall Component and insert a comment here in the comment field to indicate what other components it is associated with.

Planned

Who must complete planned enrollment tables:

All studies must enter planned enrollment counts unless your proposed study will use only 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 Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

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 Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

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 NOFO.

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. Populations that are vulnerable to coercion or undue influence and pregnant women, fetuses and neonates, if relevant to your study

Explain the rationale for the involvement of populations that are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers). Additionally, explain the rationale for the involvement of pregnant women, human fetuses and neonates.

Pregnant Women, Fetuses, and Neonates or Children

If the study involves subjects afforded 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 afforded 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 Human Subjects Research website.

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 training grant applicant.

Applicants who check "Yes" and are subject to the revised Common Rule 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 unless review by a sIRB would be prohibited by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

Applicants who check "Yes" and are subject only to the NIH sIRB policy 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 unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

> **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.

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.
- See the FAQ about answering "No" for this question on the Applying Electronically FAQ page.

Single IRB Plan Attachment

For NIH Applicants, the single IRB plan is no longer required. See additional information in the content section below.

For AHRQ applicants, if this is a research project that involves more than one institution and that will be conducted in the United States, Applicants 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, and include a single IRB plan as instructed below, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in AHRQ-funded, cooperative research studies are not expected to follow this requirement.

Format:

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

Although one sIRB plan attachment per application is sufficient, you must include a file for each study within your application. All filenames within your application must be unique. You may either attach the same sIRB plan (with different filenames) 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:

For NIH applicants, the single IRB plan is no longer required. Do not provide an attachment. The applicant must provide a statement naming the sIRB of record in the Just-in-Time submission prior to award.

For more information:

- NIH's Single IRB Policy for Multi-site Research page
- NIH's FAQs on Single IRB Policy for Multi-site Research

For AHRQ applicants, the single IRB plan should include the following elements:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified participating sites will agree 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 you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement 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 a 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 more information:

- AHRQ Guide Notice on Single IRB
- AHRQ Protection of Human Subjects page

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.

For AHRQ Applicants, Data and Safety Monitoring (DSM) plans are required in all non-exempt research applications when support is sought to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk.

If you seek AHRQ support to conduct non-exempt research to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk, a "Data and Safety Monitoring Plan" attachment is required.

Refer to AHRQ Data and Safety Monitoring Policy

Format:

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

Content:

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:

- Indicate how many people and what type of entity will provide the monitoring. Include such details as whether a single person, multiple people, or a data safety monitoring board will provide monitoring. Also indicate what type of entity will provide the monitoring (e.g., PD/PI, Independent Safety Monitor/Designated Medical Monitor, Independent Monitoring Committee, Safety Monitoring Committee, Data and Safety Monitoring Board, etc.).
- 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 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
- NIH Data and Safety Monitoring Policies
- NIH Policies and IC Guidance for Data and Safety Monitoring of Clinical Trials

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 optional. Refer to your specific NOFO for specific instructions on the "Overall Structure of the Study Team" attachment.

Format:

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

Content:

Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. The attachment may include information on study team composition and key roles (e.g., medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported.

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. Inputting information in this section will result in errors and will prevent your application from being accepted.

4.1. Study Design

4.1.a. Detailed Description

Enter a narrative description of the protocol. Studies differ considerably in the methods used to assign participants and deliver interventions. Describe your plans for assignment of participants and delivery of interventions. You will also need to show that your methods for sample size and data analysis are appropriate given those plans. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage. The Narrative Study Description is not meant to be a repeat of the Research Strategy.

The narrative description is limited to 32,000 characters (but typically needs only 5,000 characters), should be written in layperson's terms, and may repeat some of the information in the Research Strategy.

Note: This field matches a ClinicalTrials.gov field (Detailed Description).

For more information about formatting text entry fields, see NIH's Rules for Text Fields page.

4.1.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.)

Note: This field matches a ClinicalTrials.gov field (Primary Purpose).

4.1.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 4.1.a. Detailed 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 is limited to 200 characters.

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

Note: This field matches a ClinicalTrials.gov field. (Interventions, including Intervention Type and Intervention Name(s)).

For more information on how to answer this question for behavioral research trials, refer to the relevant FAQ .

4.1.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 or behavioral intervention, choose "N/A".

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
- N/A

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. Device and behavioral intervention studies may select "Yes" here even if the answer above is "Other".

For more information on how to answer this question for devices or behavioral interventions, refer to the relevant FAQ page.

4.1.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.)

Note: This field matches a ClinicalTrials.gov field (Interventional Study Model).

For more information: Definitions of intervention models may be found in ClinicalTrials.gov's Glossary of Common Site Terms or in the ClinicalTrials.gov's description of Study Design.

4.1.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

Note: This field matches a ClinicalTrials.gov field (Masking).

4.1.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

Note: This field matches a ClinicalTrials.gov field (Allocation).

4.2. 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.

NIH-Defined Phase III Clinical Trials: If the proposed research includes an NIH-Defined Phase III Clinical Trial, then outcomes for required analyses by sex/gender, race, and ethnicity should be entered.

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.

Note: This field matches a ClinicalTrials.gov field (e.g., Primary Outcome Measure Information, which includes Title, Description, and Time Frame).

For more information on listing outcome measures, refer to the Human Subjects and Clinical Trials Information FAQs page..

4.3. 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 4.2 Outcome Measures.

You will need to show that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage.

4.4 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.

4.5 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).

4.5.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.

This attachment's typical length is approximately 3,000 characters.

Content:

Provide a summary describing the availability of study agents and support for the acquisition and administration of the study agent(s).

Please indicate, if applicable, the IND/IDE status of the study agent, including whether a clinical investigation is exempt from the IND/IDE requirement. Also indicate whether the investigators have had any interactions with the FDA (e.g., indicate if the FDA has stated that research may proceed). If the study agent currently has an IND/IDE number, provide that information.

Do not include the IND/IDE application, manufacturer's product specifications, study protocol, or protocol amendments in this attachment.

Additional information such as FDA letters or correspondence with the FDA may be requested in the NOFO.

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.

4.6 Is this an applicable clinical trial under FDAAA?

Select "Yes" or "No" to indicate whether the study is an applicable clinical trial (ACT) under the Food and Drug Administration Amendments Act (FDAAA).

For more information:

- NIH Glossary's definition of an applicable clinical trial
- FAQs on the ClinicalTrials.gov & FDAAA
- ClinicalTrials.gov FAQs

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 filenames 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 organization 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 the Dissemination Plan attachment.

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

For more information:

- See the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
- See the NIH Guide Notice on the Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants
- See the NIH Grants Policy Statement, Section 4.1.3.1 NIH Policy on 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 NOFO 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. Inputting information in this section will result in errors and will prevent your application from being accepted.

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.

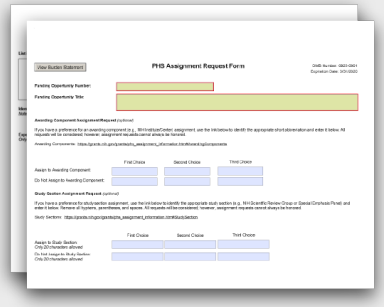
Content:

Provide additional trial-related information only if your NOFO specifically requests it. Include only attachments requested in the NOFO, and use requested filenames. If a specific filename is not given in the NOFO, use a meaningful filename since it will become a bookmark in the assembled application image. Each attachment included in the application must have a unique filename. Do not use the same file name in multiple study records. If the NOFO requires a specific filename, add unique numbers at the end of the filenames for each study record (e.g. study_filename1, study_ filename2). File name sizes are limited to 50 characters.

M.600 - PHS Assignment Request Form

The PHS Assignment Request Form may be used to communicate specific application assignment and review preferences 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.



View larger image

Completing the PHS Assignment Request Form:

This form is optional. Use it only if you wish to communicate specific awarding component assignments or review preferences. There is no requirement that all fields or all sections be completed. You have the flexibility to make a single entry 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 Suggestions (optional)

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

All assignment suggestions will be considered; however, not all assignment suggestions can 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 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 three boxes of the "Awarding Component Assignment Suggestions" section.

Suggested Awarding Component(s):

You may enter up to three preferences for primary assignment in the boxes in the "Suggested Awarding Component(s)" row. **Note:** Your application will be assigned based on the most appropriate match between it, the terms of the NOFO, and the mission of each possible awarding component, with your preference(s) taken into consideration when possible.

Suggestions must be listed in the "Components of Participating Organizations" of the NOFO, or R&R Cover Form Box 4B must list an appropriate Notice of Special Interest.

Study Section Assignment Suggestions (optional)

To facilitate accurate communication of any review assignment preferences to NIH referral and review staff, use the short abbreviation of the SRG/SEP you would prefer. For example, enter "CAMP" for the NIH Cancer Molecular Pathobiology study section or enter "ZRG1HDMR" for the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to remove all hyphens, parentheses, and spaces when you type in the suggestion. Freeform text (such as "special emphasis panel" or "member conflict SEP") should not be entered.

All suggestions will be considered; however, not all assignment suggestions can be honored.

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, depending on existing locus of review agreements within NIH and other PHS agencies. This limits flexibility for honoring assignment preferences.

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

Suggested Study Sections:

You may enter up to three preferences for SRGs/SEPs in the boxes in the "Suggested Study Sections" row. Use one box per individual SRG/SEP preference suggestion. All review preferences will be considered. **Note:** Your application will be assigned based on the most appropriate match between it, the terms of the NOFO, and the guidelines for each SRG/SEP, with your preference(s) taken into consideration when possible.

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

Rationale for assignment suggestions (optional)

Enter the rationale (i.e., why you think the assignment is appropriate) for your Awarding Component and Study Section suggestions.

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.

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

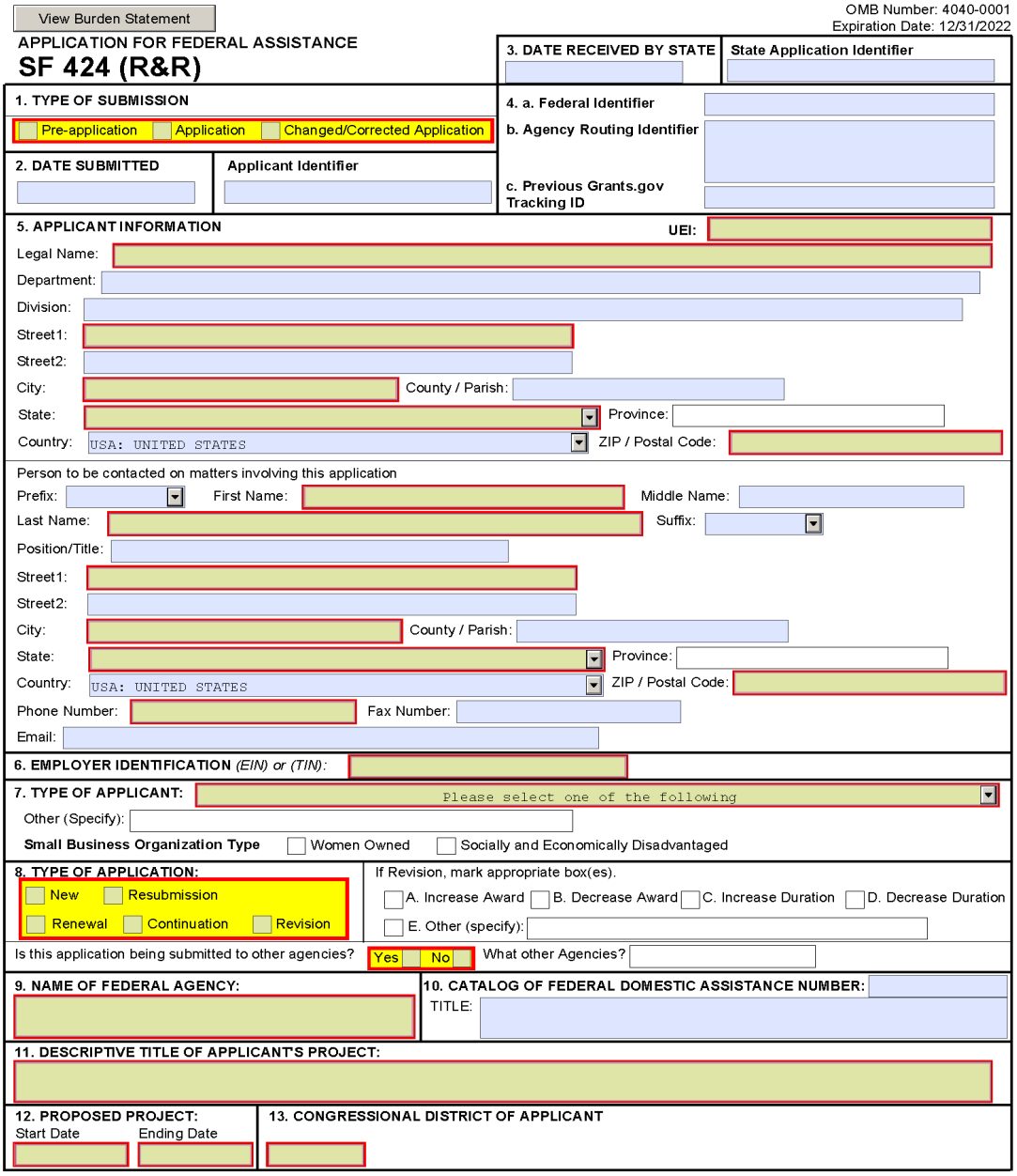
You may list specific individuals, if any, who should not review your application and why they should not review your application. Provide sufficient information (e.g., name, organizational affiliation) so that the SRO can correctly identify the individual. Be prepared to provide additional information 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.

Form Screenshots

Quick Links

SF 424 (R&R) Form



View Burden Statement

OMB Number: 4040-0001
Expiration Date: 12/31/2022

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
UEI:
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

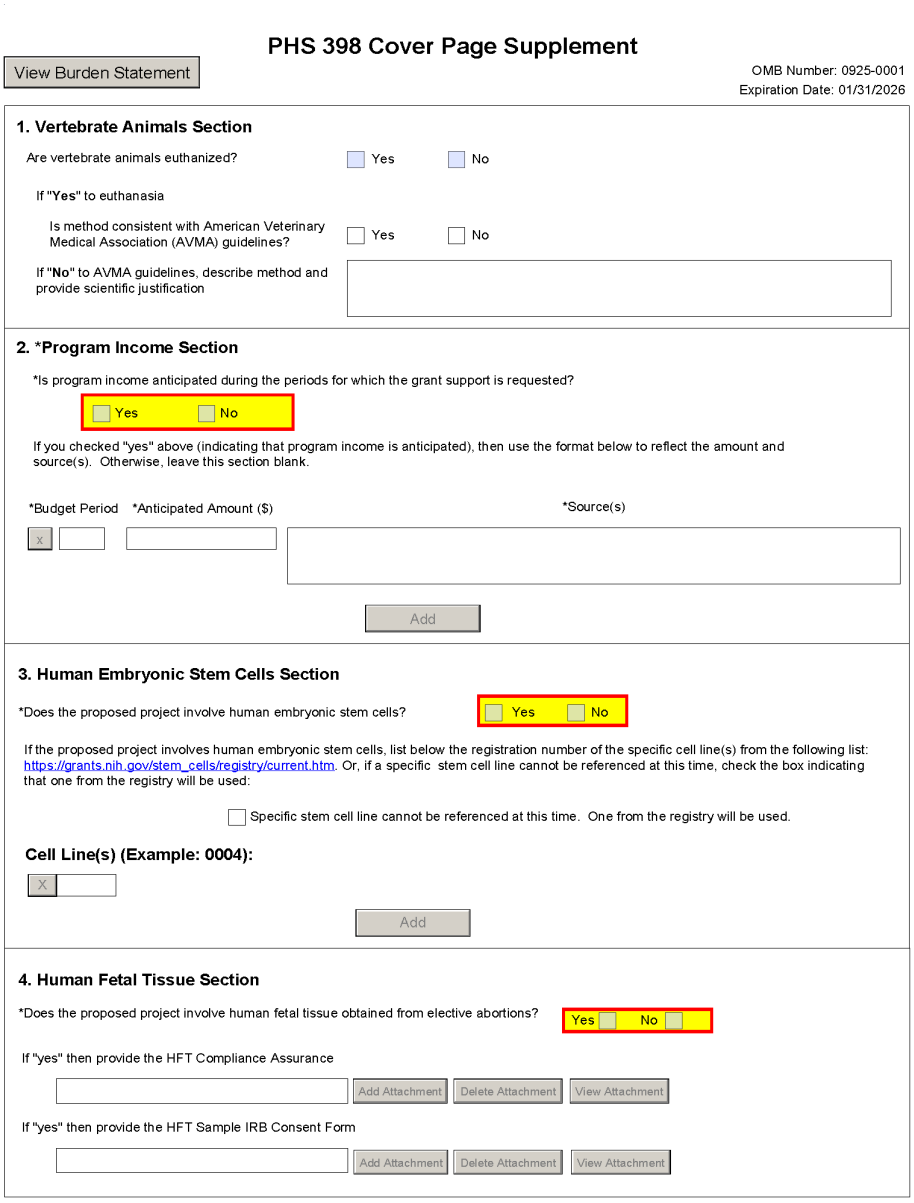
Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization:
Department:
Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

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

PHS 398 Cover Page Supplement Form



PHS 398 Cover Page Supplement

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 01/31/2026

1. Vertebrate Animals Section

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

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

Yes No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

Add

3. Human Embryonic Stem Cells Section

*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: https://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

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

Cell Line(s) (Example: 0004):

Add

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? Yes No

If "yes" then provide the HFT Compliance Assurance

Add Attachment Delete Attachment View Attachment

If "yes" then provide the HFT Sample IRB Consent Form

Add Attachment Delete Attachment View Attachment

PHS 398 Cover Page Supplement

5. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents: Yes ☐ No ☐

If "**Yes**" then answer the following:

*Previously Reported: Yes ☐ No ☐

6. Change of Investigator/Change of Recipient Organization Section

☐ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:
*First Name:
Middle Name:
*Last Name:
Suffix:

☐ Change of Recipient Organization

*Name of former organization:

R&R Other Project Information Form

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 12/31/2022

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

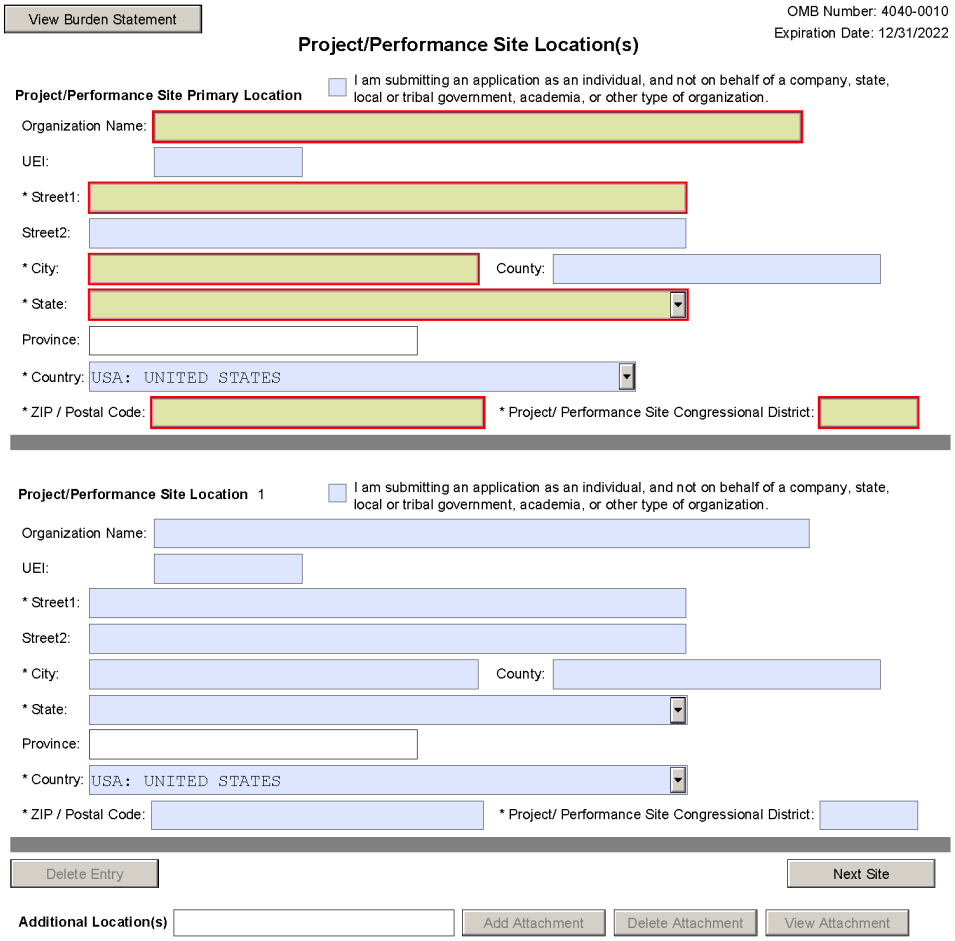
9. Bibliography & References Cited Add Attachment | Delete Attachment | View Attachment

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

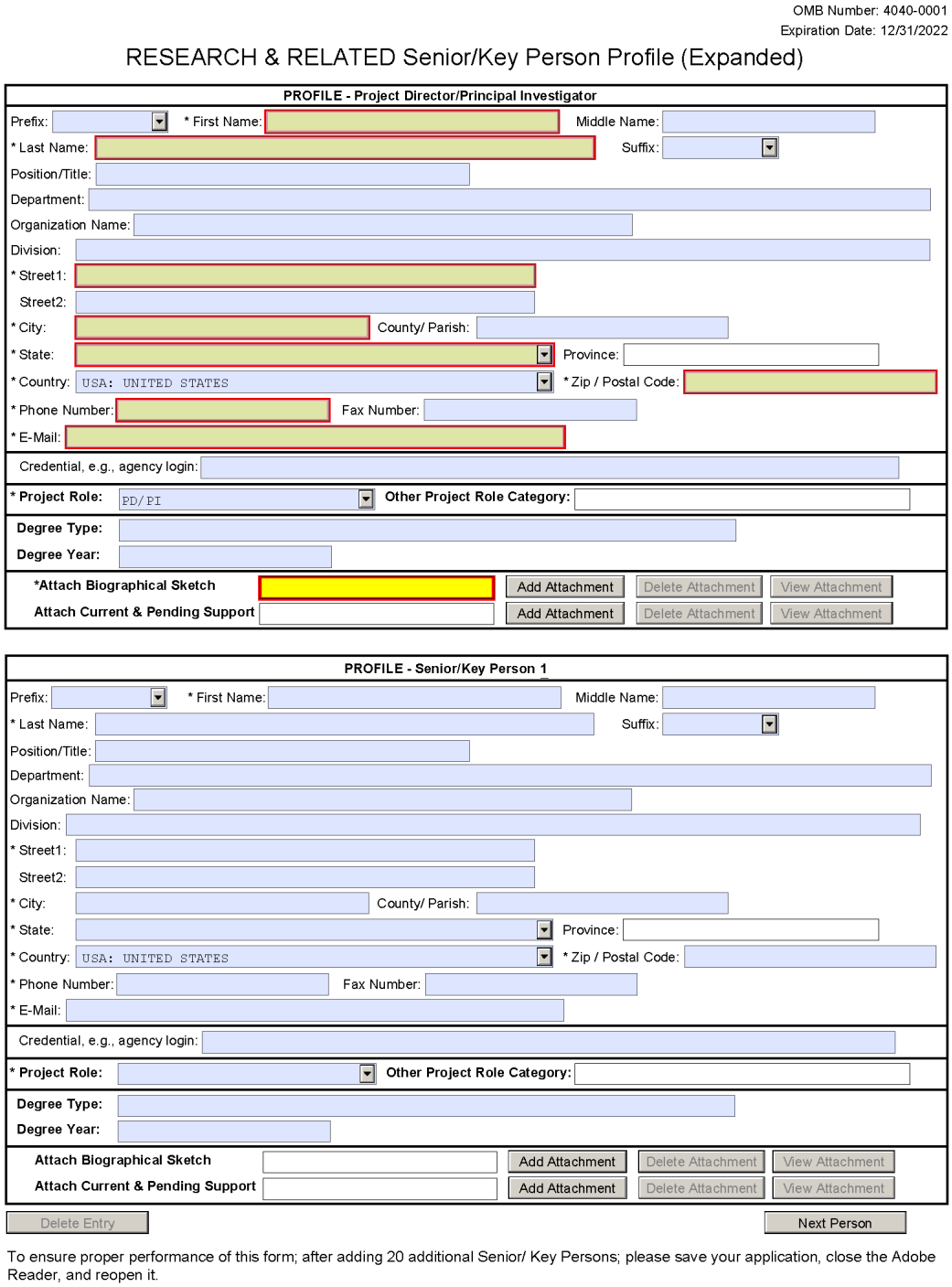
11. Equipment Add Attachment | Delete Attachment | View Attachment

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

Project/Performance Site Location(s) Form



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



OMB Number: 4040-0001
Expiration Date: 12/31/2022

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

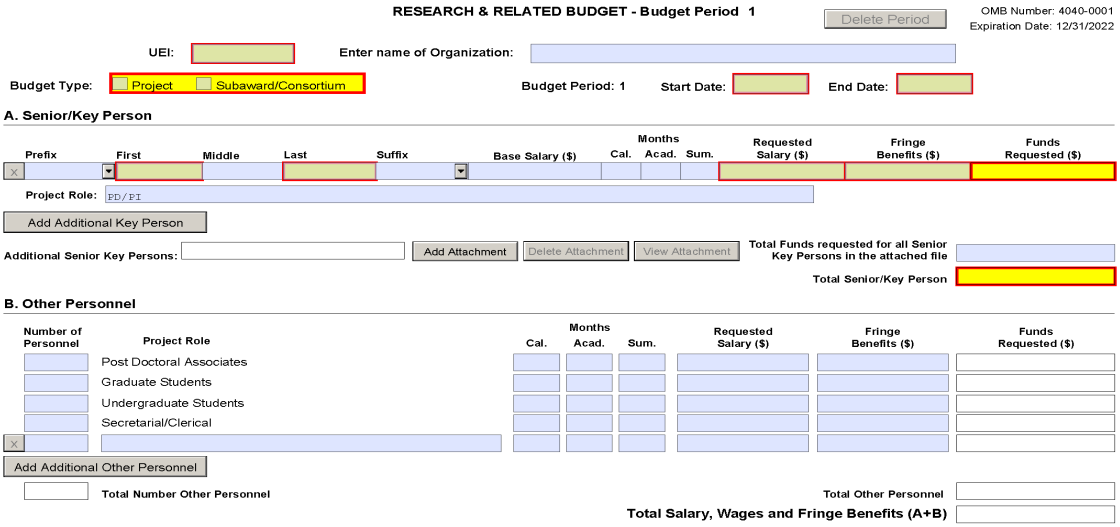
PROFILE - Senior/Key Person 1

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.

R&R Budget Form


RESEARCH & RELATED BUDGET - Budget Period 1

Delete Period

OMB Number: 4040-0001
Expiration Date: 12/31/2022

UEI: Enter name of Organization:

Budget Type: Project Subaward/Consortium Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)

Project Role: PD/PI

Add Additional Key Person

Additional Senior Key Persons: Add Attachment Delete Attachment View Attachment

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Add Additional Other Personnel

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)


C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)

Add Additional Equipment

Additional Equipment: Add Attachment Delete Attachment View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	Total Participant/Trainee Support Costs

F. Other Direct Costs — Funds Requested ($)

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8.
9.
10.
11.
12.
13.
14.
15.
16.
17.

Total Other Direct Costs

G. Direct Costs — Funds Requested ($)

Total Direct Costs (A thru F)

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
X				

Add Additional Indirect Cost

Total Indirect Costs

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs — Funds Requested ($)

Total Direct and Indirect Institutional Costs (G + H)

J. Fee — Funds Requested ($)

K. Total Costs and Fee — Funds Requested ($)

Total Costs and Fee (I + J)

L. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

Add Period

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
11. Other 4		
12. Other 5		
13. Other 6		
14. Other 7		
15. Other 8		
16. Other 9		
17. Other 10		

Section G, Direct Costs (A thru F)	
Section H, Indirect Costs	
Section I, Total Direct and Indirect Costs (G + H)	
Section J, Fee	
Section K, Total Costs and Fee (I + J)	

R&R Subaward Budget Attachment(s) Form

OMB Number: 4040-0001
Expiration Date: 12/31/2022

10 YEAR R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the 10 Year R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the 10 Year R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the 10 Year R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1		Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2		Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4		Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5		Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6		Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7		Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8		Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9		Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10		Add Attachment	Delete Attachment	View Attachment

PHS 398 Training Budget Form

View Burden Statement

PHS 398 TRAINING BUDGET, Period 1

OMB Number: 0925-0001
Expiration Date: 09/30/2024

UEI: Budget Type: Project Subaward/Consortium

See Cumulative

Organization Name:

Start Date: End Date:

A. Stipends, Tuition/Fees

Number of Trainees: Full Time	Short Term		Stipends Requested ($)	Tuition/Fees Requested ($)
		Undergraduate:		
		Number Per Stipend Level: First-Year/Soph. Junior/Senior		
		Predoctoral: Single Degree		
		Dual Degree		
		Total Predoctoral		
		Postdoctoral: *Number Per Stipend Level:* 0 1 2 3 4 5 6 7		
		Non-degree Seeking		
		Degree Seeking		
		Total Postdoctoral		
		Other:		
		Totals:		
		Total Stipends + Tuition/Fees Requested		

B. Other Direct Costs

	Funds Requested ($)
Trainee Travel	
Training Related Expenses	
Total Direct Costs from R&R Budget Form (if applicable)	
Consortium Training Costs (if applicable)	
Total Other Direct Costs Requested	

C. Total Direct Costs Requested (A + B)

D. Indirect (F&A) Costs

	Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base	Funds Requested ($)
1.				
2.				
			Total Indirect (F&A) Costs Requested	

E. Total Direct and Indirect (F&A) Costs Requested (C + D)

F. Budget Justification ? Add Attachment Delete Attachment View Attachment

Add Period

Previous

PHS 398 TRAINING BUDGET, Cumulative Budget

A. Stipends, Tuition/Fees

		Stipends Requested ($)	Tuition/Fees Requested ($)
Undergraduate:			
Predoctoral:	Single Degree		
	Dual Degree		
	Total Predoctoral		
Postdoctoral:	Non-Degree Seeking		
	Degree Seeking		
	Total Postdoctoral		
Other:			
	Totals:		
	Total Stipends + Tuition/Fees Requested		

B. Other Direct Costs

	Funds Requested ($)
Trainee Travel	
Training Related Expenses	
Total Direct Costs from R&R Budget Form (if applicable)	
Consortium Training Costs (if applicable)	
Total Other Direct Costs Requested	

C. Total Direct Costs Requested (A + B)

D. Total Indirect (F&A) Costs Requested

E. Total Direct and Indirect (F&A) Costs Requested (C + D)

PHS 398 Training Subaward Budget Attachment(s) Form

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 09/30/2024

TRAINING SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions:

This form allows you to attach a PHS 398 Training Budget form for each subaward/consortium associated with your application. Use the "Click here to extract the PHS 398 Training Subaward Attachment" button to extract a blank copy of the PHS 398 Training Budget form, complete the form in accordance with the agency instructions, and attach the completed form using one of the "Add Attachment" buttons.

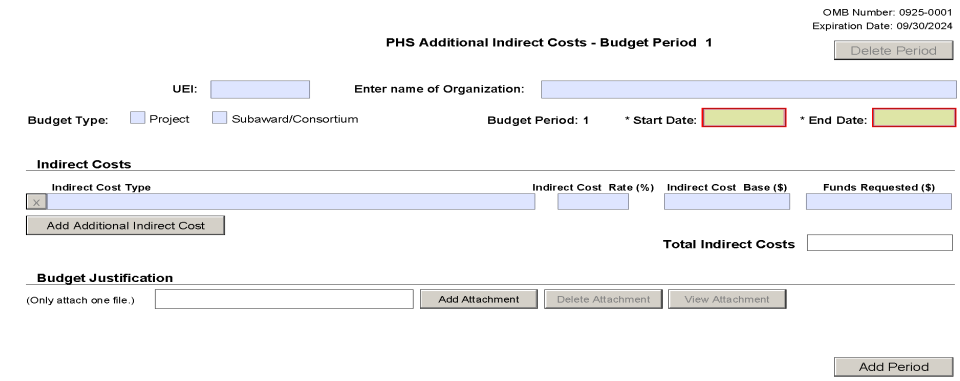
Click here to extract the PHS 398 Training Subaward Attachment

Important:

Attach Training Subaward Budget forms, using the blocks below. Remember that the files you attach must be PHS 398 Training Budget PDF forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

Attach Training Subaward Budget 1		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 2		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 3		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 4		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 5		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 6		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 7		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 8		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 9		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 10		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 11		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 12		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 13		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 14		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 15		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 16		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 17		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 18		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 19		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 20		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 21		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 22		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 23		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 24		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 25		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 26		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 27		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 28		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 29		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 30		Add Attachment	Delete Attachment	View Attachment

PHS Additional Indirect Cost Form



OMB Number: 0925-0001
Expiration Date: 09/30/2024

PHS Additional Indirect Costs - Budget Period 1

Delete Period

UEI: Enter name of Organization:

Budget Type: Project Subaward/Consortium Budget Period: 1 * Start Date: * End Date:

Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
x			

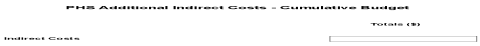
Add Additional Indirect Cost

Total Indirect Costs

Budget Justification

(Only attach one file.) Add Attachment Delete Attachment View Attachment

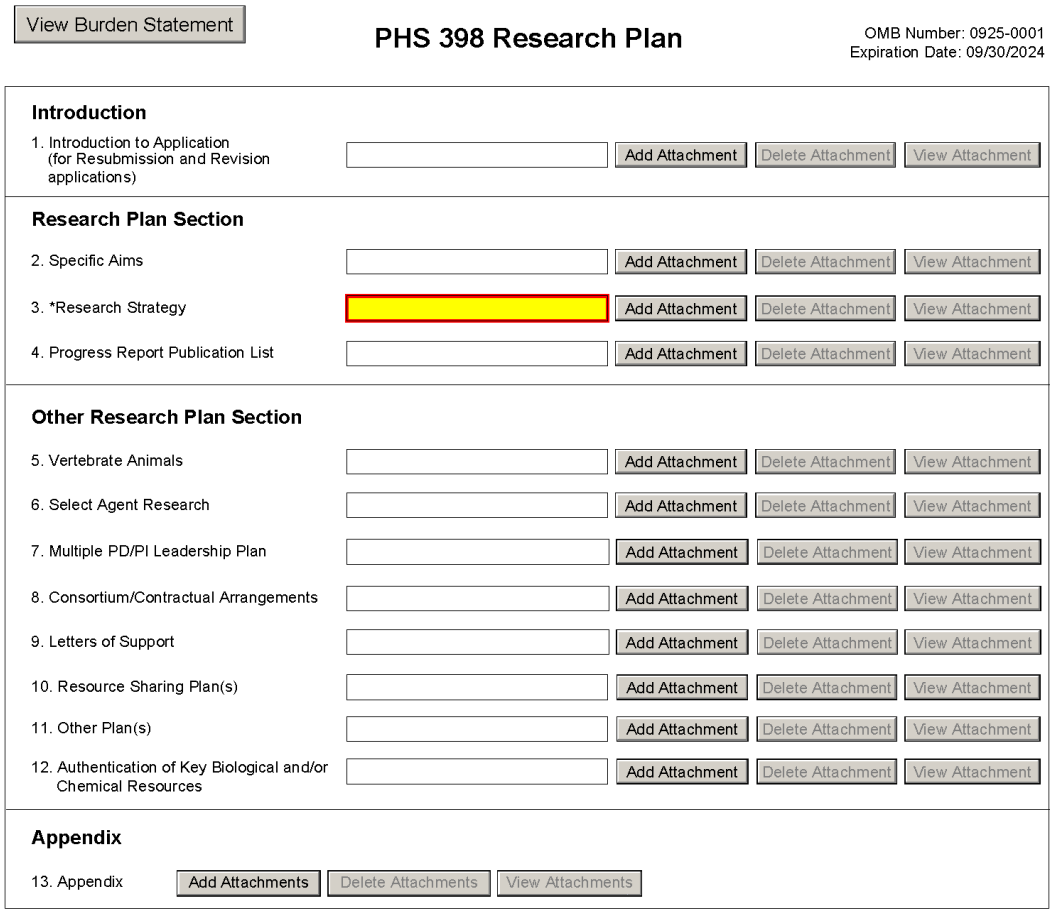
Add Period



PHS Additional Indirect Costs - Cumulative Budget

	Totals ($)
Indirect Costs	

PHS 398 Research Plan Form



View Burden Statement

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 09/30/2024

Introduction

1. Introduction to Application (for Resubmission and Revision applications)		Add Attachment	Delete Attachment	View Attachment

Research Plan Section

2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment

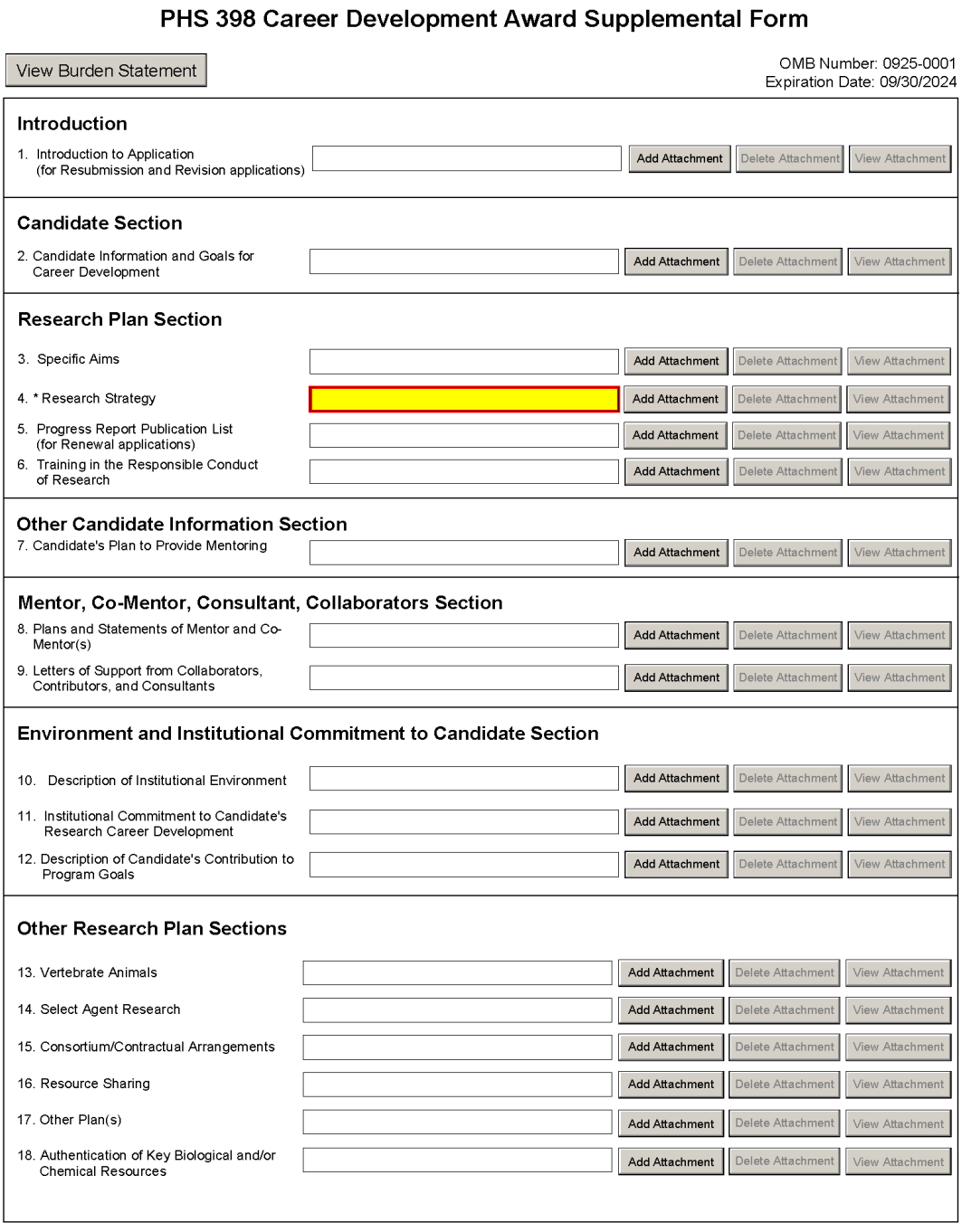
Other Research Plan Section

5. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
6. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
7. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
8. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
9. Letters of Support		Add Attachment	Delete Attachment	View Attachment
10. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
11. Other Plan(s)		Add Attachment	Delete Attachment	View Attachment
12. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

Appendix

13. Appendix	Add Attachments	Delete Attachments	View Attachments

PHS 398 Career Development Award Supplemental Form



PHS 398 Career Development Award Supplemental Form

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 09/30/2024

Introduction

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

Candidate Section

2. Candidate Information and Goals for Career Development — Add Attachment | Delete Attachment | View Attachment

Research Plan Section

3. Specific Aims — Add Attachment | Delete Attachment | View Attachment
4. * Research Strategy — Add Attachment | Delete Attachment | View Attachment
5. Progress Report Publication List (for Renewal applications) — Add Attachment | Delete Attachment | View Attachment
6. Training in the Responsible Conduct of Research — Add Attachment | Delete Attachment | View Attachment

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring — Add Attachment | Delete Attachment | View Attachment

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s) — Add Attachment | Delete Attachment | View Attachment
9. Letters of Support from Collaborators, Contributors, and Consultants — Add Attachment | Delete Attachment | View Attachment

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment — Add Attachment | Delete Attachment | View Attachment
11. Institutional Commitment to Candidate's Research Career Development — Add Attachment | Delete Attachment | View Attachment
12. Description of Candidate's Contribution to Program Goals — Add Attachment | Delete Attachment | View Attachment

Other Research Plan Sections

13. Vertebrate Animals — Add Attachment | Delete Attachment | View Attachment
14. Select Agent Research — Add Attachment | Delete Attachment | View Attachment
15. Consortium/Contractual Arrangements — Add Attachment | Delete Attachment | View Attachment
16. Resource Sharing — Add Attachment | Delete Attachment | View Attachment
17. Other Plan(s) — Add Attachment | Delete Attachment | View Attachment
18. Authentication of Key Biological and/or Chemical Resources — Add Attachment | Delete Attachment | View Attachment

PHS 398 Career Development Award Supplemental Form

Appendix

19. Appendix

Add Attachments | Delete Attachments | View Attachments

* Citizenship

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

If no, select most appropriate Non-U.S. Citizen option

☐ With a Permanent U.S. Resident Visa

☐ With a Temporary U.S. Visa

☐ Not Residing in the U.S.

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: ☐

PHS 398 Research Training Program Plan Form

View Burden Statement

PHS 398 Research Training Program Plan

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Introduction

1. Introduction to Application (for Resubmission and Revision applications)		Add Attachment	Delete Attachment	View Attachment

Training Program Section

2. * Program Plan		Add Attachment	Delete Attachment	View Attachment
3. Recruitment Plan to Enhance Diversity		Add Attachment	Delete Attachment	View Attachment
4. Plan for Instruction in the Responsible Conduct of Research		Add Attachment	Delete Attachment	View Attachment
5. Plan for Instruction in Methods for Enhancing Reproducibility		Add Attachment	Delete Attachment	View Attachment
6. Multiple PD/PI Leadership Plan (if applicable)		Add Attachment	Delete Attachment	View Attachment
7. Progress Report (for Renewal applications)		Add Attachment	Delete Attachment	View Attachment

Faculty, Trainees and Training Record Section

8. Participating Faculty Biosketches		Add Attachment	Delete Attachment	View Attachment
9. Letters of Support		Add Attachment	Delete Attachment	View Attachment
10. Data Tables		Add Attachment	Delete Attachment	View Attachment

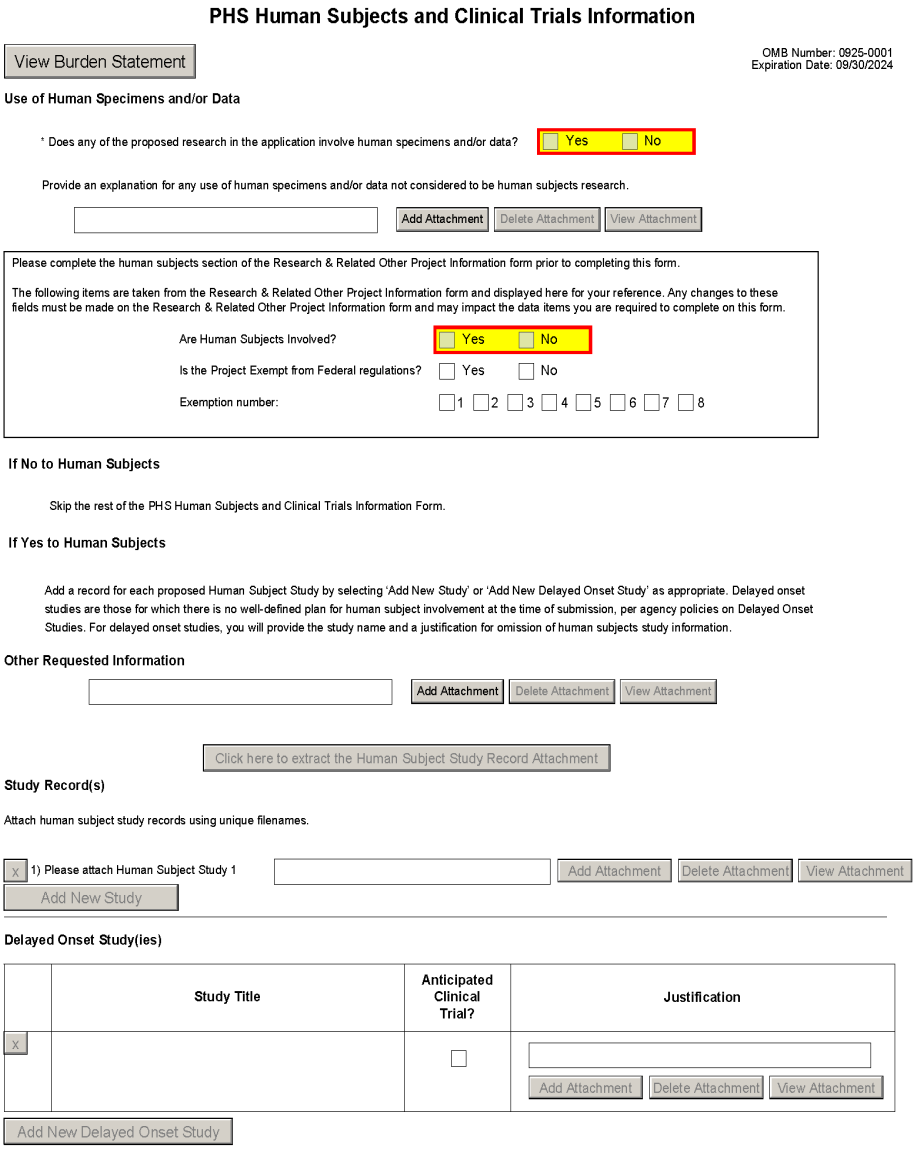
Other Training Program Section

11. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
12. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
13. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
14. Other Plan(s)		Add Attachment	Delete Attachment	View Attachment

Appendix

15. 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: 09/30/2024

Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data? Yes No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Add Attachment | Delete Attachment | View Attachment

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 09/30/2024

* 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**

2.3.a. Inclusion of Individuals Across the Lifespan Add Attachment | Delete Attachment | View Attachment

2.4. Inclusion of Women and Minorities 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 Participant

2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

OMB Number: 0925-0770
Expiration Date: 09/30/2024

Inclusion Enrollment Report

Remove Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

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

3. * Enrollment Location Type ☐ Domestic ☐ Foreign

4. Enrollment Country(ies)

Add New Country

5. Enrollment Location(s)

6. Comments

Planned

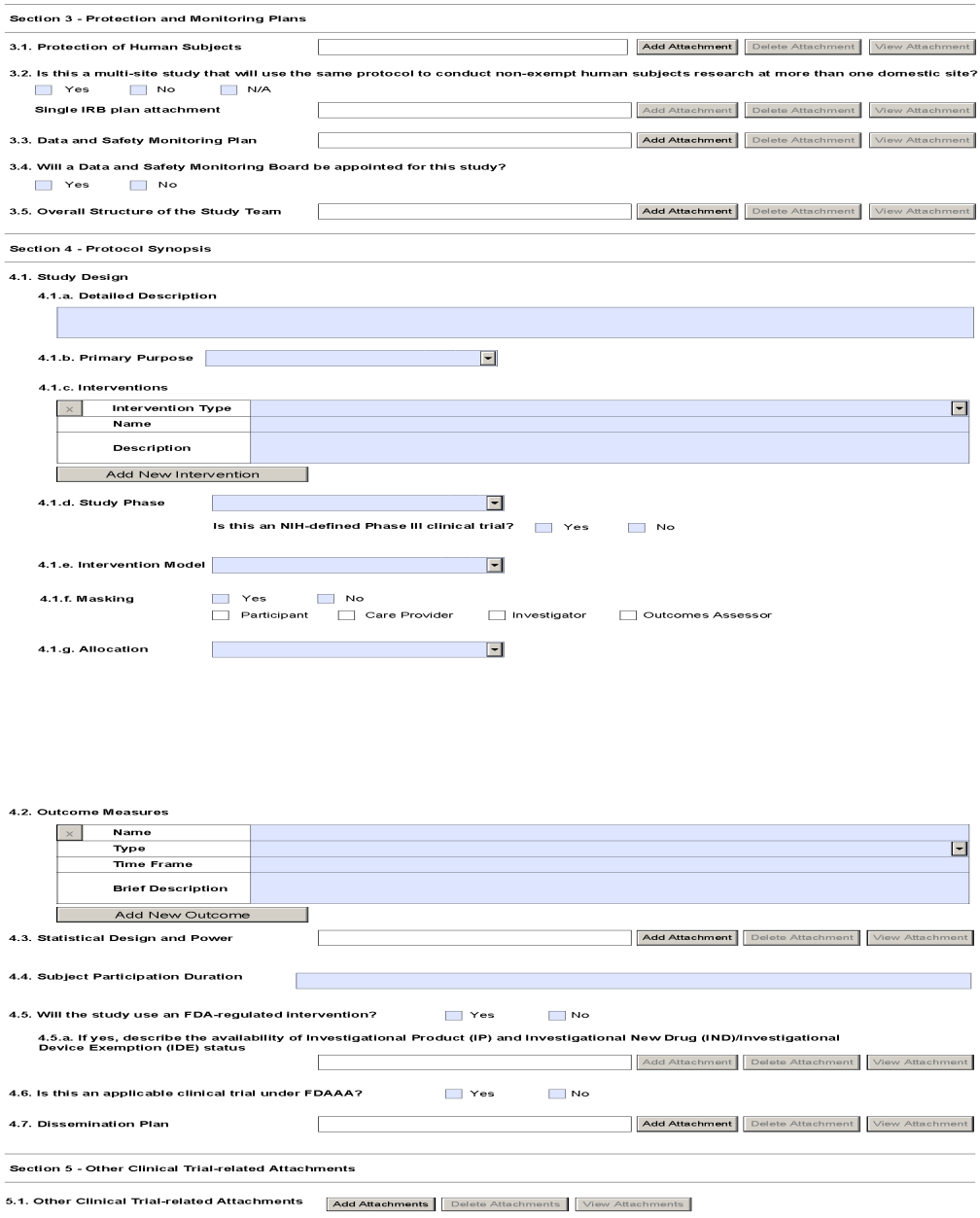
Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0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

Cumulative (Actual)

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

Single IRB plan attachment — 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. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Intervention Type	
Name	
Description	

Add New Intervention

4.1.d. Study Phase

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

4.1.e. Intervention Model

4.1.f. Masking — Yes No

Participant Care Provider Investigator Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Name	
Type	
Time Frame	
Brief Description	

Add New Outcome

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

4.4. Subject Participation Duration

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

4.5.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

4.6. Is this an applicable clinical trial under FDAAA? Yes No

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: 01/31/2026

Awarding Component Assignment Suggestions *(optional)*
Verify your suggested awarding component(s) (e.g., NIH Institute/Center) participate(s) in the Funding Opportunity. Use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below. All requests will be considered; however, assignment suggestions cannot always be honored.

Suggestions must be listed in the "Components of Participating Organizations" of the NOFO, or R&R Cover Form Box 4B must list an appropriate Notice of Special Interest.

Information about Awarding Component can be found here:
https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components:

Study Section Assignment Suggestions *(optional)*
Enter the short study section code in the box below. Remove all hyphens, parentheses, and spaces. For example, enter "AIRT" to suggest the study section "Anti-Infective Resistance and Targets", or B10 to suggest "Small Business: Biobehavioral Processes – BP (10)". All requests will be considered; however, assignment suggestions cannot always be honored.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections:

Rationale for assignment suggestions *(optional)*
Explain why you think the suggestions are appropriate. If you contacted NIH staff, list their name(s). Entry is limited to 1000 characters.

Identify scientific areas of expertise needed to review your application *(optional)*
Do not provide names of individuals. Each entry is limited to 40 characters.

List individuals who should not review your application and why *(optional)*
Entry is limited to 1000 characters

PHS Assignment Request Form

List individuals who should not review your application and why *(optional)* *Entry is limited to 1000 characters*

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

Expertise:
Each entry is limited to 40 characters