FORMS VERSION D SERIES

UPDATED NOVEMBER 22, 2016

SBIR/STTR 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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B.100 - How to Use the Application Instructions

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

Take a tour of the Application Guide

Quick Links

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

Helpful Links

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

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

Step 1. Become familiar with the application process.

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

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

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

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

> Remember that the FOA instructions always supersede these application instructions.

Step 3. Choose an application instruction format.

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

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

Step 4. Complete the appropriate forms.

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

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

Step 5. Stay informed of policy changes and updates.

- Refer to the B.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.

B.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
- Format and Write
- Submission Process
- Due Dates and Submission Deadlines
- After Submission
- Resources
- Information Collection

Prepare to Apply and Register

Systems and Roles

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

Register

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

Understand Funding Opportunities

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

Types of Applications

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

Submission Options

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

Obtain Software

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

Format and Write

Write Your Application

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

Develop Your Budget

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

Format Attachments

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

Page Limits

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

Data Tables

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

Reference Letters

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

Biosketches

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

Submission Process

Submit, Track and View

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

How We Check for Completeness

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

Changed/Corrected Applications

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

Due Dates and Policies

Due Dates

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

Submission Policies

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

Dealing with System Issues

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

After Submission

Receipt and Referral

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

Peer Review

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

Pre-award Process

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

Post award Monitoring and Reporting

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

Resources

News - Items of Interest

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

Annotated Form Sets

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

Contacting NIH Staff

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

Contacting Staff at Other PHS Agencies

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

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.

B.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 22, 2016

How to Apply - Application Guide and Format Page Changes

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

Plain Language Edits to Application Instructions

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

Form Instruction Changes

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

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

R&R Budget

- Instructions added for "K. Total Costs and Fee" field included in preparation for future form use.
- The letter label ("K or L.") for the "Budget Justification" section will vary depending on the version of the form included in the application package.

PHS 398 Cover Page Supplement

- Instructions have changed so that program income and stem cell information are no longer collected at the Overall Component in multi-project applications.
  - A system-generated summary of all program income and stem cell information that is provided in Other Components will be included in the summaries section of the assembled application image.

PHS 398 Research Plan

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

Revision Notes - June 10,2016

- Formatting changes to B.100 - How to use the Application Instructions.
- Corrected typos throughout instructions for greater clarity.
- Removed language regarding the 1 page limit for career development applications in the Project Summary/Abstract field in B.220 - R&R Other Project Information Form. The standard instruction of no more than 30 lines of text applies.
- Clarifications made to multi-project application instructions in B.210 - PHS 398 Cover Page Supplement Form.

Release Notes - March 25, 2016

Application Guide Restructure

- **Forms reordered.** Form instructions have been reordered to match the order of appearance in the application package.
- **Consolidated instructions.** SBIR/STTR instructions have been incorporated into the general instructions.
- **Separated form instructions from application process information.** Created an application guide landing page that provides at-a-glance access to all form instructions and application process information. Links to all grants process information appear in the form instructions as well.
- **Combined and streamlined instructions.** For Research and Related (R&R) forms, we have combined Federal-wide and agency-specific instructions to reduce confusion, contradictions, and/or redundant language. Users will no longer see the HHS logo displayed, as all instructions are now applicable to NIH and PHS agencies.
- **Better integrated mechanism-specific instructions.** Variances in instructions for each type of grant program (research, career development, etc.), are now called out and integrated in the general instructions to make them easy to follow.
- **New mechanism-specific views of application guide.** Use the General (G) instructions to see instructions for all mechanisms in one place. Take advantage of the filtered views to see just the instructions you need for research (R), career development (K), training (T), fellowship (F), multi-project (M) or SBIR/STTR (B) applications.
- **New section numbering system.** Form instructions will follow the same numbering system for each set of instructions. For example, the SF 424 (R&R) Cover Form will always be ".100," and the letter preceding it will reflect the specific instructions you are using. For the General (G) instructions, this form will be located in G.100; for the Research (R) instructions, this will be R.100; and so on.
- **New page numbering system.** Page numbers will denote which set of instructions you are looking at (e.g., G - 56 for page 56 of the General instructions; R - 56 for page 56 of the Research (R) instructions; etc.). This distinction will be important when you reference a particular instruction.
- **Form screenshots.** Provided at the end of each set of instructions for your reference.

SF424 Research and Related (R&R) Form Changes

R&R Other Project Information Form

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

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

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

Forms-D Changes

PHS 398 Cover Page Supplement

- New Vertebrate Animals section added:
  - Are animals euthanized? Yes/No
  - If Yes, is method consistent with AVMA guidelines? Yes/No
  - If No to AVMA guidelines, describe method/provide scientific justification
- "Disclosure Permission Statement" question removed
- Ability to add Program Income information for 10 budget periods (previously 5)
- Field order and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS 398 Research Plan

- New "Data Safety Monitoring Plan" attachment
- New "Authentication of Key Biological and/or Chemical Resources" attachment
- Minor format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Assignment Request Form

- New, optional form

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

PHS Inclusion Enrollment Report

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

B.130 - Program Overview

Quick Links

- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)

The SBIR and STTR programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.

Additional Instructions for SBIR/STTR:

Additional SBIR/STTR instructions will be denoted by a gray call-out box with purple color coding and with the heading "Additional Instructions for SBIR/STTR" throughout these application instructions.

New to SBIR/STTR?

View our SBIR/STTR Application Process Infographic.

View the Three-Phase Program description page.

Confirm Small Business Eligibility Criteria.

Develop an Innovative Research Idea with Commercial Potential

Determine which SBIR/STTR funding opportunity announcement (FOA) is most appropriate for your idea. The Omnibus SBIR/STTR solicitations allow researchers to submit their own ideas to NIH. Targeted SBIR/STTR FOAs are more focused around specific research areas. Before starting the application process, you should speak with an HHS SBIR/STTR representative at the NIH IC or PHS agency to which you are applying.

Required Registrations

The registration process may take 6 – 8 weeks, so it is important to start early. Learn about the Electronic Submission Process, including the SBA Company Registration, which is unique to SBIR/STTR applicants. Small businesses are encouraged to submit via ASSIST.

Three Phase Program:

Both the SBIR and STTR programs are divided into three phases:

- **Phase I:** Feasibility and Proof of Concept,
- **Phase II:** Research/Research and Development, and

- **Phase III:** Commercialization.

Additionally, the Commercialization Readiness Pilot (CRP) Program uses SBIR funding (as such, applicants must be an SBIR-eligible Small Business), and follows all Phase II instructions (although it is not a Phase I, II, IIB, or III award).

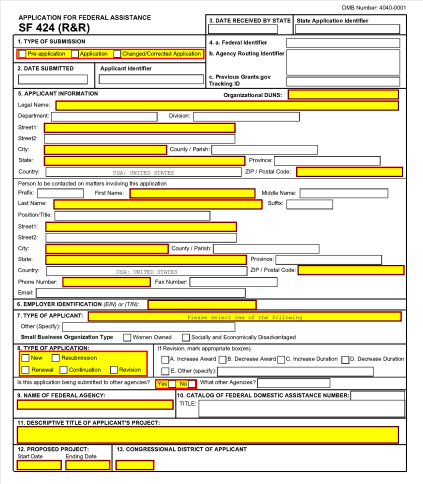
The chart below provides a summary of details for each of those phases.

Application Name	Definition	Budget / Time Guidelines*	Participating HHS Component	Commercialization Plan?	Grant Type
Phase I	Establish the technical merit and feasibility of the proposed R&D efforts	$150,000 total costs, 6 - 12 months	NIH, CDC, FDA, ACF	No	New/Resub
Fast-track	One application for Phase I and Phase II that is submitted and reviewed together	$150,000 + $1,000,000 total costs, 2.5-3 years	NIH	Yes	New/Resub
Direct Phase II (SBIR Only)	Bypass Phase I if feasibility studies are completed	$1,000,000 total costs, for 2 years	NIH	Yes	New/Resub
Phase II	Full R&D Award	$1,000,000 total costs, for 2 years	NIH, CDC, FDA, ACF	Yes	Renewal
Phase IIB	For projects that require extraordinary time and effort in the R&D phase	$1,000,000 total costs per year for up to 3 years	NIH	Yes	Renewal
Commercialization Readiness (CRP) Pilot Program	The CRP may fund commercialization activities that are not typically supported through SBIR/STTR Phase II or Phase IIB awards. **Must have Phase II or IIB to apply**	Up to $300,000 or $3 million for up to 2 or 3 years	NIH, CDC	Yes	Renewal
Phase III	Commercialization activities (eg: Direct sales, partnerships, licensing deals, mergers and acquisitions)	N/A	Typically not supported by HHS	N/A	N/A

* At NIH, deviations from the budget guidelines are acceptable, but must be well justified and discussed with NIH program staff prior to application submission. According to statutory guidelines, total funding support (direct costs, indirect costs, and fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards; however, with appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% as a hard cap ($225,000 for Phase I and $1,500,000 for Phase II). However, NIH has also received a waiver from SBA, as authorized by the statute, to exceed the hard cap (of $225,000 for Phase I and $1,500,000 for Phase II) for specific topics. The list of approved topics can be found on the SBIR/STTR Funding page. Applicants are strongly encouraged to contact program officials prior to submitting any application in excess of the guidelines and early in the application planning process. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

B.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.



OMB Number: 4040-0001

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE | State Application Identifier

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

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

2. DATE SUBMITTED | Applicant Identifier

5. APPLICANT INFORMATION | Organizational DUNS:
Legal Name:
Department: | Division:
Street1:
Street2:
City: | County / Parish:
State: | Province:
Country: USA: UNITED STATES | ZIP / Postal Code:
Person to be contacted on matters involving this application.
Prefix: | First Name: | Middle Name:
Last Name: | Suffix:
Position/Title:
Street1:
Street2:
City: | County / Parish:
State: | Province:
Country: USA: UNITED STATES | ZIP / Postal Code:
Phone Number: | Fax Number:
Email:

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

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

8. TYPE OF APPLICATION:
New | Resubmission
Renewal | Continuation | Revision
If Revision, mark appropriate box(es).
A. Increase Award | B. Decrease Award | C. Increase Duration | D. Decrease Duration
E. Other (Specify):
Is this application being submitted to other agencies? Yes | No | What other Agencies?

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date | Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

View larger image

Quick Links

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

4a. Federal Identifier

4b. Agency Routing Identifier

4c. Previous Grants.gov Tracking ID

5. Applicant Information
6. Employer Identification
7. Type of Applicant
8. Type of Application
9. Name of Federal Agency
10. Catalog of Federal Domestic Assistance Number and Title
11. Descriptive Title of Applicant's Project
12. Proposed Project
13. Congressional District of Applicant
14. Project Director/Principal Investigator Contact Information
15. Estimated Project Funding
16. Is Application Subject to Review by State Executive Order 12372 Process?
17. Certification
18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation
19. Authorized Representative
20. Pre-application
21. Cover Letter Attachment

1. Type of Submission

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

Pre-application:

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

Application:

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

Changed/Corrected Application:

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

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

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

Additional Instructions for SBIR/STTR:

SBIR/STTR Phase II/IIB Applications: To maintain eligibility to seek Phase II or IIB support, a Phase I awardee should submit a Phase II application, and a Phase II awardee should submit a Phase IIB application, within the first six due dates following the expiration of the Phase I or II budget period, respectively.

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).

Additional Instructions for SBIR/STTR:

When submitting a Phase II application, enter the Phase I SBIR/STTR grant number in this field.

For more information on applying for SBIR/STTR Phase II or Phase IIB awards, see SBIR/STTR Frequently Asked Questions.

4.b. Agency Routing Identifier

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

4.c. Previous Grants.gov Tracking ID

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

5. Applicant Information

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

Additional Instructions for SBIR/STTR:

The small business concern is always the applicant organization for an SBIR or STTR award (e.g., ABC Incorporated).

The small business concern must be located in the United States.

Organizational DUNS:

This field is required.

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

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

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

Legal Name:

Enter the legal name of the organization.

Department:

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

Division:

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

Street1:

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

Street2:

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

City:

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

County/Parish:

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

State:

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

Province:

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

Country:

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

ZIP/Postal Code:

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

Person to be contacted on matters involving this application

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

Prefix:

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

First Name:

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

Middle Name:

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

Last Name:

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

Suffix:

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

Position/Title:

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

Street1:

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

Street2:

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

City:

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

County/Parish:

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

State:

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

Province:

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

Country:

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

ZIP/Postal Code:

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

Phone Number:

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

Fax Number:

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

E-mail:

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

6. Employer Identification

This field is required.

Enter either the organization's Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) as assigned by the Internal Revenue Service. If your organization is not in the United States, enter 44-4444444. Your EIN may be 12 digits, and if this is the case, enter all 12 digits.

Additional Instructions for SBIR/STTR:

The small business must be located in the United States or a U.S. territory.

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 SBIR/STTR:

Select "R. Small Business." Also note whether the organization is Woman-owned and/or Socially and Economically Disadvantaged.

The applicant organization must certify (through Just-in-Time pre-award procedures) that it will qualify as a small business concern at the time of award.

Other (Specify):

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

Women Owned:

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

Socially and Economically Disadvantaged:

Check this box only if both "Small Business" is selected as the "Type of Applicant" and it is applicable. Socially and economically disadvantaged status is determined by the U.S. Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).

8. Type of Application

This field is required.

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

- **New.** Check this option when submitting an application for the first time or in accordance with other submission policies. See the NIH Guide Notice on the Updated Policy for Application Submission.
- **Resubmission.** Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH Application Submission Policies. If your application is both a "New/Revision/Renewal" and a "Resubmission," check only the "Resubmission" box.
- **Renewal.** Check this option if you are requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as if the applicant were applying for the first time.
- **Continuation.** The box for "Continuation" is used only for specific FOAs.
- **Revision.** Check this option for competing revisions and non-competing administrative supplements. For more information on competing revisions, see NIH Competing Revisions. For more information on administrative supplements, see NIH Administrative Supplements.

Additional Instructions for SBIR/STTR:

For more information about SBIR/STTR application types, see the SBIR/STTR Frequently Asked Questions.

If Revision, mark appropriate box(es).

You may select more than one.

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

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

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

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

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

Otherwise, check "No."

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

For additional information, see the NIH Guide Notice on the Updated Application Submission Policy.

9. Name of Federal Agency

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

10. Catalog of Federal Domestic Assistance Number and Title

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

This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant's Project

This field is required.

Enter a brief descriptive title of the project.

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

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

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

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

Additional Instructions for SBIR/STTR:

An SBIR/STTR Phase II application should have the same title as the previously awarded Phase I grant.

12. Proposed Project

Start Date:

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

Ending Date:

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

Additional Instructions for SBIR/STTR:

Phase I: Routinely, SBIR Phase I awards do not exceed six months, and STTR Phase I awards do not exceed one year.

Phase II and Commercialization Readiness Pilot (CRP): Routinely, both SBIR and STTR Phase II awards do not exceed two years.

Under special circumstances, applicants to NIH may propose longer periods of time for completion of the research project (e.g., feasibility demonstration). Such requests must be thoroughly justified. Project duration deviations apply to NIH only, as CDC, FDA, and ACF do not make awards for periods longer than the stated guidelines.

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

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

Additional Instructions for SBIR/STTR:

For Single PD/PI Applications: Name the one person responsible to the applicant small business concern (SBC) for the scientific and technical direction of the project in the "14. PD/PI Contact Information" section.

For Multiple PD/PI Applications: Name the contact PD/PI here in "14. PD/PI Contact Information." The Contact PD/PI (as designated here in "14. PD/PI Contact Information") must be listed first in the B.240 - R&R Senior/Key Person Profile (Expanded) Form and must be affiliated with the applicant organization in the PD/PI's eRA Commons profile.

NIH and PHS staff conduct official business only with the named PD/PIs and organizational/institutional officials.

A revision/supplemental application must have the same contact PD/PI as the currently funded grant.

SBIR

Phase I, Phase II, and CRP: The primary employment of the PD/PI must be with the SBC at the time of award and during the conduct of the proposed project. Primary employment means that more than one half (greater than 50%) of the PD/PI's time is spent in the employ of the SBC. Primary employment with an SBC precludes full-time employment at another organization. Occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator. For purposes of the SBIR Program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA's size regulations, 13 CFR 121.106-Small Business Size Regulations.

Phase I, Phase II, and CRP Multiple PD/PI applications: The PD/PI listed here in "14. PD/PI Contact Information" must be affiliated with the applicant SBC organization submitting the application and will serve as the contact PD/PI. The primary employment of the "Contact PD/PI" must be with the SBC at the time of award and during the conduct of the proposed project. As noted above, occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

PD/PI Definition: As defined in 42 CFR 52, the PD/PI(s) is or are the "...individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project." When the proposed PD/PI clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation.

Verification of PD/PI Eligibility: If the application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the PD/PI, if at the time of submission of the application, the PD/PI meets any of the following criteria:

- is a less-than-full-time employee of the SBC;

- is concurrently employed by another organization;
- gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

If the PD/PI is employed or appears to be employed by an organization other than the applicant organization in any capacity (such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate), a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant SBC, the PD/PI is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the PD/PI is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

This requirement applies also to those individuals engaged currently as the PD/PI on an active SBIR project. All current employment and all other appointments of the PD/PI must be identified in his or her "Biographical Sketch" required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

STTR

Phase I and Phase II: The primary employment of the principal investigator must be with the SBC or the research institution at the time of award and during the conduct of the proposed project. Primary employment means that more than one half (greater than 50%) of the PD/PI's time is spent in the employ of the SBC or the research institution. Primary employment with an SBC or research institution precludes full-time employment at another organization. An SBC may replace the principal investigator on an STTR Phase I or Phase II award, subject to approval in writing by the Funding Agreement Officer. For purposes of the STTR Program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA's size regulations, 13 CFR 121.106—Small Business Size Regulations.

For Multiple PD/PI Applications: The PD/PI listed here in "14. PD/PI Contact Information" must be affiliated with the applicant SBC submitting the application and will serve as the Contact PD/PI. The Contact PD/PI may be from either the SBC or the single partnering research institution. Note: the Contact PD/PI must have a formal appointment with or commitment to the SBC, which must be in the form of an official relationship between the parties, but need not include a salary or other form of remuneration.

PD/PI Eligibility: The PD/PI must commit a minimum of 10% (1.2 calendar months) effort to the project and must have a formal appointment with or commitment to the applicant SBC, which is characterized by an official relationship between the SBC and that individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the PD/PI's official relationship with the grantee must entail sufficient opportunity for the PD/PI to carry out his or her responsibilities for the overall scientific and technical direction of the project. Although documentation (e.g., consortium and contractual arrangements) describing the official relationship of the PD/PI with the applicant SBC should NOT

be submitted with the grant application, a copy must be furnished upon the request of the NIH awarding component.

Following is guidance for such documentation (describing the official relationship of the PD/PI with the applicant SBC), which is required prior to award. The letter should be prepared on the letterhead of the independent PD/PI and addressed to the SBC. One page is recommended. At a minimum, the letter should (1) verify the PD/PI's commitment to the project; (2) refer to the specific project by name; and (3) specify what assets or services the PI will contribute (e.g. expertise, number of hours/percent effort) as well as the PD/PI's remuneration. The letter should also indicate that the PD/PI and the SBC have reached an agreement on proprietary interests (e.g., intellectual property).

Signatures of the authorized organization representative (AOR or signing official) for the applicant organization on the Authorized Representative section and the signature of the duly authorized representative of the research institution certifies, among other things, that the PD/PI has a formal relationship with/commitment to the SBC when the PD/PI is an employee of the Research Institute.

The following are examples of situations describing the official relationship of the PD/PI with the applicant small business organization:

- PD/PI with a full-time, university appointment may also have appointments with other organizations (with or without salary) and still appropriately consider his or her commitment to the university to be "full-time," consistent with the personnel policies and procedures of the university applied on aroutine basis. The PD/PI's commitment to the university and other organizations (including the applicant SBC) cannot exceed 100% of his or her total professional effort.
- PD/PI with a full-time, 12-month appointment with an SBC would be considered to have a commitment to the applicant organization of 100% of his or her total professional effort.
- PD/PI who has a part-time appointment with an SBC and has concurrent commitments or appointments with organizations in addition to the small business concern would deem each commitment as a portion of 100% of his or her total professional effort.

As responsible stewards of funds, the NIH is concerned that the PD/PI has the time available to carry out the proposed STTR research activities. Therefore, it should be clear in the application that the time proposed for the PD/PI on a particular project is reasonable and it should be clear that the PD/PI has sufficient time (minimum 10% effort, which is 1.2 calendar months) from among his or her total professional commitments to devote to this project.

Prefix:

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

First Name:

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

Middle Name:

Enter the middle name of the PD/PI.

Last Name:

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

Suffix:

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

Position/Title:

Enter the position/title of the PD/PI.

Organization Name:

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

Department:

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

Division:

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

Street1:

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

Street2:

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

City:

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

County/Parish:

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

State:

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

Province:

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

Country:

Select the country for the PD/PI.

ZIP/Postal Code:

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

Phone Number:

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

Fax Number:

Enter the fax number for the PD/PI.

E-mail:

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

15. Estimated Project Funding

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

a. Total Federal Funds Requested

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

Additional Instructions for SBIR/STTR:

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

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap). As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding $225,000 for Phase I or $1,500,000 for Phase II, if this hard cap will interfere with NIH's ability to meet its mission. Award waivers from the SBA are not guaranteed and may delay the release of funds. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project. Note: CDC, FDA, and ACF do not make awards above these statutory guidelines.

b. Total Non-Federal Funds

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

c. Total Federal & Non-Federal Funds

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

d. Estimated Program Income

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

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

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

17. Certification

This field is required.

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

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal and/or civil penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

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

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

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

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

For more information:

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

19. Authorized Representative

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

Prefix:

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

First Name:

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

Middle Name:

Enter the middle name of the AOR/SO.

Last Name:

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

Suffix:

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

Position/Title:

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

Organization Name:

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

Department:

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

Division:

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

Street1:

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

Street2:

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

City:

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

County/Parish:

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

State:

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

Province:

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

Country:

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

ZIP/Postal Code:

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

Phone Number:

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

Fax Number:

Enter the fax number for the AOR/SO.

Email:

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

Signature of Authorized Representative:

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

It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov.

Date Signed:

Grants.gov will generate this date upon application submission.

20. Pre-application

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

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

21. Cover Letter Attachment

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

Who must complete the "Cover Letter Attachment:"

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

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

Format:

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

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

Content:

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

1. Application title.
2. Title of FOA (PA or RFA).
3. For late applications (see Late Application policy on NIH's 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 B.310 – R&R Subaward Budget Attachment(s) Form).

6. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications that request $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc. It is recommended that you include the official communication from an NIH official as part of your cover letter attachment.
7. When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, the video will not be accepted. See NIH Guide Notice on the Interim Guidance for Videos Submitted as NIH Application Materials for additional information.
8. Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy (see the NIH Guide Notices on the Implementation of the NIH Genomic Data Sharing Policy and Reminder about the Implementation of the Genomic Data Sharing Policy).

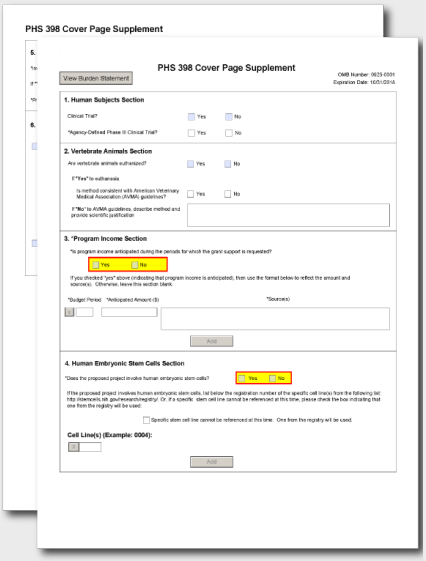
Additional Instructions for SBIR/STTR:

If Phase I or Phase II was a contract or awarded from another federal agency, include the contract or award number.

B.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 institution.

View larger image



Quick Links

1. Human Subjects Section
2. Vertebrate Animals Section
3. Program Income Section
4. Human Embryonic Stem Cells Section
5. Inventions and Patents Section (RENEWAL)
6. Change of Investigator/Change of Institution Section

1. Human Subjects Section

Clinical Trial?

An answer to this question is required if you answered “Yes” to the question “Are human subjects involved?” on the B.220 – R&R Other Project Information Form.

Check "Yes" or "No" to indicate whether the project includes a clinical trial. See NIH Glossary for the definition of clinical trials.

Agency-Defined Phase III Clinical Trial?

An answer to this question is required if you answered “Yes” to the “Clinical Trial?” question above. Check “Yes” or “No” to indicate whether the project is or includes an NIH-defined Phase III clinical trial. See NIH Glossary for the definition of Phase III clinical trial.

2. 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 B.220 – R&R Other Project Information Form.

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

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.

3. 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 "3. Program Income" section.

If no program income is anticipated, check "No" and skip the rest of the "3. Program Income" section.

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.

4. Human Embryonic Stem Cells Section

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

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

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 "4. Human Embryonic Stem Cells" section.

If the proposed project does not involve hESC, check "No" and skip the rest of the "4. Human Embryonic Stem Cells" section.

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

If you will use hESC but a specific line from the NIH hESC Registry cannot be chosen at the time of application submission, check this box.

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 SBIR/STTR:

If you cannot choose an appropriate cell line from the registry at this time, provide a justification in the B.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.

5. Inventions and Patents Section (RENEWAL)

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 grantee is required to submit reports electronically using iEdison. See the NIH Guide Notice on the Requirement to Submit Invention Disclosures, Related Reports and Documents.

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 Institution 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 Grantee Institution:

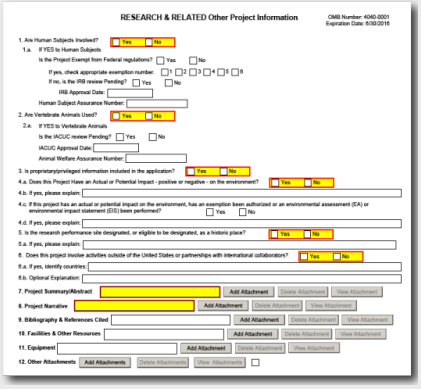
Check this box if your application reflects a change in grantee institution from that indicated on your previous application or award. This question is not applicable to new applications.

Name of Former Institution:

Enter the name of the former institution if this application reflects a change in grantee institution.

B.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.


RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 6/30/2016

1. Are Human Subjects Involved? Yes No
1.a. If YES to Human Subjects
Is the Project Exempt from Federal regulations? Yes No
If yes, check appropriate exemption number. 1 2 3 4 5 6
If no, is the IRB review Pending? Yes No
IRB Approval Date:
Human Subject Assurance Number:
2. Are Vertebrate Animals Used? Yes No
2.a. If YES to Vertebrate Animals
Is the IACUC review Pending? Yes No
IACUC Approval Date:
Animal Welfare Assurance Number:
3. Is proprietary/privileged information included in the application? Yes No
4.a. Does this Project Have an Actual or Potential Impact - 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

View larger image

Quick Links

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

1. Are Human Subjects Involved?

This field is required.

If activities involving human subjects are planned at any time during the proposed project at any performance site, check “Yes.” Check “Yes” even if the proposed project is exempt from regulations for the Protection of Human Subjects, or if activities involving human subjects are anticipated within the period of award but plans are indefinite.

If activities involving human subjects are not planned at any time during the proposed project at any performance site, select "No" and skip the rest of the "1. Are Human Subjects Involved" section.

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

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

Additional Instructions for SBIR/STTR:

If you have answered "Yes" to the "Are Human Subjects Involved?" question, you must also complete the Protection of Human Subjects attachment in B.400 - PHS 398 Research Plan Form, Protection of Human Subjects.

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? Yes/No

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

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

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

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

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

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

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

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

The Office of Human Research Protections (OHRP) guidance states that appropriate use of exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (for more information, see OHRP's Frequently Asked Questions). Institutions often designate their Institutional Review Board (IRB) to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

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

If IRB review is pending, check "Yes."

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

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

IRB Approval Date:

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

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

Human Subject Assurance Number:

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

Enter "None" if the applicant organization does not have an approved FWA on file with OHRP. In this case, the applicant organization, by the signature in the Certification section on the B.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.

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 SBIR/STTR:

If you have answered "Yes" to the "Are Vertebrate Animals Used?" question, you must also provide an explanation and anticipated timing of animal use in B.400 - PHS 398 Research Plan Form, Vertebrate Animal. This attachment must be submitted and reviewed prior to the involvement of animals in any research studies.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

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

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

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

IACUC Approval Date:

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

An IACUC approval date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under Supplemental Instructions, Part III, Section 1.7: Just-in-Time Policy.

Animal Welfare Assurance Number

Enter the federally approved assurance number, if available.

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

To determine whether the applicant organization holds an Animal Welfare Assurance with an associated number, see the lists of Domestic and Foreign Assured institutions. Also note the NIH Guide Notice on the Animal Welfare Assurance Numbering System, effective July 2016. **Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution.**

When an applicant organization does *not* have an Animal Welfare Assurance number, the authorized organization representative's signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW.

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

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

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

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

This field is required.

Patentable ideas; trade secrets; or privileged, confidential commercial, or financial information should be included in applications only when such information is necessary to convey an understanding of the proposed project.

If the application includes such information, check "Yes" and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a statement similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the government, except for purposes of review and evaluation." This statement can be included at the top of each page as applicable.

If a grant is awarded as a result of or in connection with the submission of this application, the government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the NIH and other PHS agencies will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield

the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR 5). Additionally, if an applicant fails to identify proprietary information at the time of submission as instructed here, a significant substantive justification will be required to withhold the information if requested under FOIA.

4. Environmental Questions

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

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

This field is required.

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

Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer "No" unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following scenarios, check "Yes."

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

4.b. If yes, please explain:

If you answered "Yes" to Question 4.a., you must provide an explanation here as to the actual or potential impact of the proposed research on the environment.

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

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

4.d. If yes, please explain:

Enter additional details about the EA or EIS here.

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

This field is required.

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

5.a. If yes, please explain:

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

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

This field is required.

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

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

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

6.a. If yes, identify countries:

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

6.b. Optional Explanation:

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

7. Project Summary/Abstract

The "Project Summary/Abstract" attachment is required.

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

Format:

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

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

Content:

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe the research design and methods for achieving the stated goals. Be sure that the project summary reflects the key focus of the proposed project so that the application can be appropriately categorized.

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

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

8. Project Narrative

The "Project Narrative" attachment is required.

Content:

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

9. Bibliography & References Cited

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

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

Format:

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

Content:

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

Additional Instructions for SBIR/STTR:

The "Bibliography & References Cited" attachment should include any references cited in B.400 - PHS 398 Research Plan Form.

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." NIH maintains a list of such journals.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

10. Facilities & Other Resources

Format:

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

Content:

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations or how studies will employ useful collaborative arrangements.

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

Describe any special facilities used for working with biohazards and any other potentially dangerous substances. **Note: Information about select agents must be described in the Research Plan, Select Agent Research.**

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

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

Additional Instructions for SBIR/STTR:

The research to be performed by the applicant small business concern and its collaborators must be in United States facilities that are available to and under the control of each party for the conduct of each party's portion of the proposed project. Foreign sites must be approved by the funding officer.

11. Equipment

The "Equipment" attachment is required.

Format:

Attach this information as a PDF file.

Content:

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

12. Other Attachments

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

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

Additional Instructions for SBIR/STTR:

SBA Company registry (for both SBIR and STTR):
All applicants to the SBIR and STTR programs are required to attach proof of registration with the SBA Company Registry in Question 12. Other Attachments. You will receive a unique SBC Control ID and SBA Registry file (in PDF format) when you complete your SBC Company Registration. This is the file you must attach in Question 12. Other Attachments. Applicants who have previously registered must also attach proof of registration.

To complete SBA Registration: The SBA Company Registry recommends verification with System for Award Management (SAM), but a SAM account is not required to complete the registration. In order to be verified with SAM, your email address must match one of the contacts in SAM. If you are unsure what is listed in SAM for your company, you may verify the information on the SAM site. Confirmation of your company's DUNS is necessary to verify your email address in SAM. Follow the following steps to register.

- Navigate to the SBA Company Registry.
- If you are a previous SBIR/STTR awardee from any agency, search for your small business by Company Name, EIN/Tax ID, DUNS, or Existing SBIR/STTR Contract/Grant Number in the search fields provided. Identify your company and click "Proceed to Registration."
- Fill out the required information on the "Basic Information" and "Eligibility Statement" screens.
- Press "Complete Registration" on the lower right of the "Eligibility Statement" screen and follow all instructions.Press "Complete Registration" on the lower right of the "Eligibility Statement" screen and follow all instructions.

- Download and save your SBA registry PDF locally. The name will be in the format of SBC_123456789.pdf, where SBC_123456789 (9-digit number) is your firm's SBC Control ID. DO NOT CHANGE OR ALTER THE FILE NAME. Changing the file name may cause delays in the processing of your application.
- Attach this SBA registry PDF in Question 12.

For questions and for technical assistance concerning the SBA Company Registry, contact SBA.

NIH, CDC SBIR and CRP Only:

SBIR Application Certification for small business concerns that are majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms (e.g. majority VCOC-owned): You are required to submit a Certification with your application per the SBIR Policy Directive. Follow the instructions below.

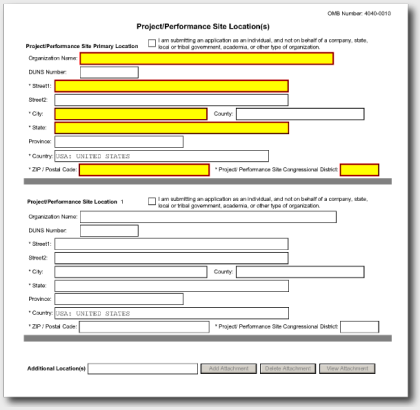
Certain applicant small business concerns do not have to fill out the Certification. Applicant small business concerns that are more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), or any combination of these (i.e. NOT majority VCOC-owned) should NOT fill out this certification and should NOT attach it to their application package.

- Download the "SBIR Application VCOC Certification.pdf" at the NIH Forms & Applications page.
- Answer the 3 questions and check the certification boxes.
- The authorized business official must sign the certification.
- Save the certification using the original file name ("SBIR Application VCOC Certification.pdf). DO NOT CHANGE OR ALTER THE FILE NAME. Changing the file name may cause delays in the processing of your application.
- Attach this Certification PDF in Question 12.

B.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


OMB Number: 4040-0010

Project/Performance Site Location(s)

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

Additional Location(s) Add Attachment Delete Attachment View Attachment

Quick Links

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

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

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

Project/Performance Site Primary Location

Generally, the primary location should be that of the applicant organization or identified as 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 B.220 - R&R Other Project Information Form.

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

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

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

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

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

Additional Instructions for SBIR/STTR:

Describe any consortium/contractual arrangements in the "Consortium/Contractual Arrangements" attachment in B.400 – PHS 398 Research Plan Form.

One of the performance sites indicated must be that of the applicant small business concern (SBC).

Phase I, Phase II, and CRP Applications: The research or R&D project activity must be performed in the United States. However, based on a rare and unique circumstance (for example, if a supply or material or the study design [e.g., patient population] is not available in the United States), NIH may allow that particular portion of the research or R&D work to be performed or obtained in a foreign sponsorship country. Investigators must thoroughly justify the use of these sites in the application. These rare and unique situations will be considered on a case-by-case basis, and they should be discussed with NIH staff prior to submission of the application. Approval by the funding officer for such specific condition(s) must be in writing prior to issuance of an award. Whenever possible, non-SBIR/STTR funds should be used for other work outside of the United States that is necessary to the overall completion of the project.

The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of the SBIR/STTR grantee for the conduct of its portion of the proposed project. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR/STTR awardee has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project.

Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, the awarding component will request that the SBC provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space. This letter must be signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project and must certify that the SBC (grantee organization) will have access to and control over the research space. In addition, the letter must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the grantee organization. If the letter is included with the application, it is excluded from the page limitations. Attach this letter to the B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

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

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

otherwise specified by the FOA.

Organization Name:

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

DUNS Number:

This field is required for the primary performance site.

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

Street1:

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

Street2:

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

City:

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

County:

Enter the county of the primary performance site location.

State:

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

Province:

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

Country:

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

ZIP/Postal Code:

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

Project/Performance Site Congressional District:

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

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

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

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

For jurisdictions with no representative, enter "099."

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

If all districts in a state are affected, enter “all” for the district number. Example: "MD-all" for all congressional districts in Maryland.

If nationwide (all districts in all states), enter "US-all."

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

Project/Performance Site Location 1

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

Organization Name:

Enter the organization name of the performance site location.

DUNS Number:

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

Street1:

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

Street2:

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

City:

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

County:

Enter the county of the performance site location.

State:

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

Province:

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

Country:

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

ZIP/Postal Code:

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

Project/Performance Site Congressional District:

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

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

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

For jurisdictions with no representative, enter "099."

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

If all districts in a state are affected, enter "all" for the district number. Example: "MD-all" (for all congressional districts in Maryland).

If nationwide (all districts in all states), enter "US-all."

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

Additional Locations

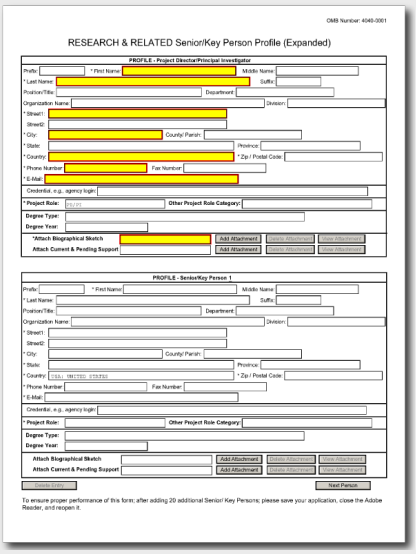
If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the "Additional Locations" section.

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

B.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 B.200 - SF 424 (R&R) Form if these fields are empty.

View larger image



Quick Links

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

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

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

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

Who qualifies as a Senior/Key Person?

Unless otherwise specified in a FOA, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included in this "Senior/Key Person Profile (Expanded)" Form if they meet this definition.

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

Profile - Project Director/Principal Investigator

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

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

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

Additional Instructions for SBIR/STTR:

STTR Applications:
The STTR applicant organization must officially affiliate the PD/PI with the small business concern (SBC) in the eRA Commons if the PD/PI is not an employee of the SBC. For additional information on creating user affiliations in the eRA Commons, see the eRA Account Management System's Online Help.

Prefix:

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

First Name:

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

Middle Name:

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

Last Name:

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

Suffix:

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

Position/Title:

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

Department:

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

Organization Name:

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

Division:

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

Street1:

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

Street2:

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

City:

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

County/Parish:

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

State:

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

Province:

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

Country:

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

ZIP/Postal Code:

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

Phone Number:

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

Fax Number:

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

E-mail:

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

Credential, e.g., agency login:

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

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

Project Role:

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

Other Project Role Category:

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

Degree Type:

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

Degree Year:

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

Attach Biographical Sketch

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

Attach Current & Pending Support:

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

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

Instructions for a Biographical Sketch

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

Who must complete the "Biographical Sketch" section:

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

Format:

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

Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).

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

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

Content:

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

Name:

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

eRA Commons User Name:

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

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

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

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

Position Title:

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

Education/Training

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

For each entry provide:

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

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

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

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.

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

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

B. Positions and Honors

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

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

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

C. Contributions to Science

Who should complete the "Contributions to Science" section:

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

Format:

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

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

Content:

For each contribution, indicate the following:

- the historical background that frames the scientific problem;
- the central finding(s);
- the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology;
- your specific role in the described work.

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

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

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

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

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

- High school students are *not* required to complete Section D. Additional Information: Research Support and/or Scholastic Performance.
- Career development award applicants should complete the "Research Support" section but skip the “Scholastic Performance” section.
- Generally, the following types of applicants can skip the “Research Support” section and must complete **only** the “Scholastic Performance” section. However, when these applicants also have Research Support, they may complete both sections.
  - applicants for predoctoral and postdoctoral fellowships,
  - applicants to dissertation research grants,
  - candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels.

Research Support

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

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

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

- **Research Support:** As part of the Biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each your qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.
- **Other Support:** NIH staff may request complete and up-to-date "other support" information from you as part of Just-in-Time information collection.

Scholastic Performance

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

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

Profile – Senior/Key Person 1

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

Format:

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

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

Senior/Key Persons: Fill in a separate "Profile – Senior/Key Person" block for each 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:

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

Project Role:

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

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

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

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:

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

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

Additional Senior/Key Person Profile(s)

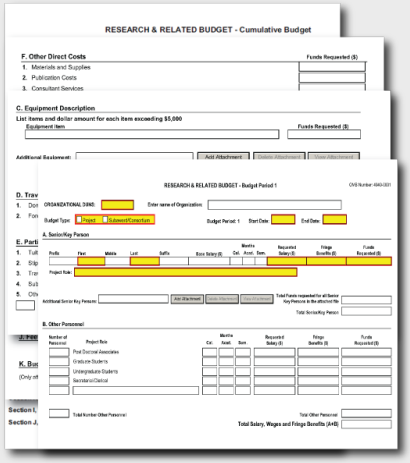
If you need to add more Senior/Key Person Profiles than the form allows, enter the information in a separate file and attach it as a PDF.

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

B.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 FOA 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

- Introductory Fields
- A. Senior/Key Person
- B. Other Personnel
- C. Equipment Description
- D. Travel
- E. Participant/Trainee Support Costs
- F. Other Direct Costs
- G. Direct Costs
- H. Indirect Costs
- I. Total Direct and Indirect Costs
- J. Fee
- K. Total Cost and Fee
- K or L. Budget Justification
- Cumulative Budget

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 FOA and to the following instructions for guidance on which Budget Form to use.

Note that 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. Some NIH Institutes/Centers (IC) do not require prior approval. For more information on applications that request $500,000 or more in direct costs, see the Supplemental Instructions, Part III,

Section 1.4: Policy on the Acceptance for Review of Unsolicited Applications that Request $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.) institutions 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. Applications from foreign organizations must request budgets in U.S. dollars.

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 B.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.

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

Organizational DUNS:

This field is required. This field may be pre-populated and should reflect the DUNS or DUNS+4 number 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 K or 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 B.310 - R&R Subaward Budget Attachment(s) Form.

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 B.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:

Details of collaborators at other institutions should not be listed 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 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 NIH Senior/Key Personnel Frequently Asked Questions.

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 institution does not use a 9-month academic year or a 3-month summer period, indicate your institution's definition of these in Section K or 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 Guide Notice on 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 B.240 - R&R Senior/Key Person Profile (Expanded) Form. Note that there must be at least one PD/PI per budget period.

Additional Instructions for SBIR/STTR:

STTR: If the budget type is "project," you do not have to list a PD/PI; list the PD/PI in the Subaward/Consortium budget.

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 K or 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.

Post Doctoral 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 K or 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 K or 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 institution does not use a 9-month academic year or a 3-month summer period, indicate your institution’s definition of these in Section K or 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 Guide Notice on 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.

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 K or L. Budget Justification. Allowable items ordinarily will be limited to research equipment not already available for the conduct of the work.

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 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 K or 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 K or 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 FOA, 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 K or 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.

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 K or L. Budget Justification.

3. Consultant Services:

List the total funds requested for all consultant services. Identify the following items in Section K or 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 K or 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 K or 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 Supplemental Instructions, Part III, Section 1.1: 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 K or 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 K or 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 institutions 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.

8-10 Other:

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

List funds requested for each of the items in lines "8-10 Other." Use lines 8-10 for costs such as patient care and tuition remission. If requesting patient care costs, request inpatient and outpatient costs separately, using lines 8 and 9.

Additional Instructions for SBIR/STTR:

Special Instructions for Technical Assistance Costs: NIH offers distinct technical assistance programs to SBIR and STTR Phase I and Phase II awardees. These programs offer specialized, strategic business training and provide access to a vast network of industry experts. If you wish to utilize your own technical assistance provider, you are required to include this as a consultant in your budget and to provide a detailed budget justification. You may request up to $5,000 for

assistance. Reimbursement is limited to services received that comply with 15 U.S.C. § 638(q):

To provide small business concerns engaged in SBIR or STTR projects with technical assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in:

- Making better technical decisions concerning such projects;
- Solving technical problems which arise during the conduct of such projects;
- Minimizing technical risks associated with such projects; and
- Developing and commercializing new commercial products and processes resulting from such projects.

To request technical assistance from your own provider:

- Label the requested cost of up to $5,000 "Technical Assistance" on one of the lines from 8-10.
- Include a detailed description of the services your vendor will provide in the Budget Justification.

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 grantee 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 Defense Finance and Accounting 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.

Additional Instructions for SBIR/STTR:

In accordance with the Small Business Innovation Development Act of 1982 and the Small Business Technology Transfer Act of 1992, irrespective of the time period in which the costs are incurred, no SBIR/STTR funds can be used to "support" any commercialization (Phase III activities). "Support" in this case includes both direct and indirect costs.

The Small Business Administration's SBIR and STTR Program Policy Directives defined terms:

SBIR agencies must establish an SBIR Program by reserving, in each fiscal year, not less than 3.2 percent (FY 2017) of its extramural budget for awards to SBCs for R/R&D. "R&D activities" include any activities directed toward reducing the technical risk of the technology.

- Commercialization. The process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to government or commercial markets.
- Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR federal agency funding.

Based on this position, when NIH is negotiating indirect costs with SBIR/STTR grantees/contractors, we are disallowing all indirect costs applicable to commercialization activities related to SBIR/STTR awards.

Commercialization cost categories: Below is a list of cost categories NIH considers to be commercialization.

- marketing and sales;
- market research;
- business development/product development/market plans;
- legal fees;
- travel and other costs relating to license agreements and partnerships; and
- labor costs for the Marketing Director and Director of Business Development, as well as sales and marketing staff who are grantee/contractor employees or contractors hired for those purposes.

Special Instructions for Foreign Organizations (Non-domestic [non-U.S. Entities]): Foreign institutions 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 K or 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."

Additional Instructions for SBIR/STTR:

If you have an indirect cost rate: If the applicant small business concern has a currently effective negotiated indirect cost rate with a federal agency, that rate should be used when calculating proposed indirect costs. However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by HHS.

If applicable, indicate your organization's most recent indirect cost rate established with NIH's Division of Financial Advisory Services (DFAS) or with another federal agency. If your applicant organization is in the process of negotiating or renegotiating a rate, use that rate in the application.

If you don't have an indirect cost rate: If the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes. Follow the guidelines below.

SBIR and STTR Phase I Applicants: If your organization does not have a currently effective negotiated indirect cost rate with a federal agency, then propose estimated F&A costs at a rate not to exceed 40% of the total direct costs. If awarded at a rate of 40% or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate. NIH will not negotiate F&A rates for Phase I awards.

SBIR and STTR Phase II and CRP Applicants: SBIR and STTR applicants who propose in the application an F&A rate of 40 percent of total direct costs or less will not be required to provide further justification at the time of award, and F&A costs will be awarded at the requested rate. However, DFAS will retain the authority to require well-documented proposals for F&A rates on an ad hoc basis. If the applicant SBC has a currently effective negotiated indirect cost rate(s) with a federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) SBCs are reminded that only actual F&A costs may be charged to projects. If awarded at a rate of 40 percent or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS. DFAS will negotiate F&A/IDC rates for SBCs receiving Phase II awards if the

requested rate is greater than 40 percent of total direct costs. For more detailed information, see NIH Guide Notice on the Negotiation of F&A/Indirect Costs for Phase II SBIR/STTR Grants.

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 Cost).

Additional Instructions for SBIR/STTR:

Award Limits: According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards.

NIH deviations from statutory guidelines: The ability to deviate from the statutory guidelines applies to NIH only. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap). As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding $225,000 for Phase I or $1,500,000 for Phase II, if this hard cap will interfere with NIH's ability to meet its mission.

Award waivers from the SBA are not guaranteed and may delay the release of funds. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

The ability to deviate from the statutory guidelines applies to NIH ONLY.

SBIR Phase I applications to CDC, FDA, and ACF are limited to a total cost of $150,000.

SBIR Phase II applications to CDC, FDA, and ACF are limited to a total cost of $1,000,000.

J. Fee

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

Additional Instructions for SBIR/STTR:

A reasonable fee, not to exceed 7% of total costs (direct and indirect) for each Phase (I and II) of the project, is available with SBIR/STTR awards. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. Explain the basis and the amount requested for the fee in Section K or L. Budget Justification.

The amount requested for the fee should be based on the following guidelines:

- it must be consistent with that paid under contracts by the PHS for similar research conducted under similar conditions of risk;
- it must take into account the complexity and innovativeness of the research to be conducted under the SBIR/STTR project; and
- it must recognize the extent of the expenditures for the grant project for equipment and for performance by other than the grantee organization through consultant and subaward agreements.

The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Note: The electronic system automatically rounds up. If you get an error "The fee must be less than 7%," try using 6.99% as the rate.

K. Total Costs and Fee

This section is not available in all application packages.

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").

K or L. Budget Justification

The letter label ("K or L.") for the "Budget Justification" section will vary depending on the application package.

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

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.

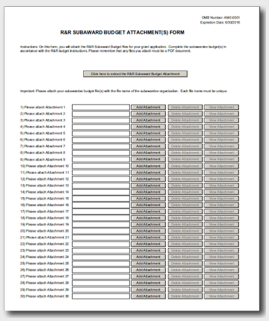
If any of the amounts displayed on this form appear to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such corrections, you will need to revisit the appropriate budget period form(s).

B.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 grantee is submitting an R&R Budget Form and has subaward/consortium budgets.

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



View larger image

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 B.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 grantee 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 (B.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 grantee's R&R Budget Form. All F&A costs count toward the direct cost limit.

Refer to the Supplemental Instructions, Part III, Section 1.1: 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.

Additional Instructions for SBIR/STTR:

These instructions on Consortium/Contractual F&A Costs do not apply.

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 B.300 - R&R Budget Form and in the B.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 Grants.gov downloadable forms, 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 B.300 – R&R Budget Form, the prime grantee 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 B.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 B.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.

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 B.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:

- Organization DUNS
- 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

Additional Instructions for SBIR/STTR:

SBIR

Phase I and Phase II: The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

Phase I: Normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern (SBC). The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A/indirect, and fee).

Phase II and CRP: Normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the SBC. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct and F&A/indirect, and fee).

STTR

Phase I and Phase II: At least 40% of the work must be performed by the SBC and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and

F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

The single "partnering" research institution must provide a letter to the applicant SBC certifying that at least 30% of the work of the STTR project will be performed by the research institution. The SBC will include this letter as an attachment upload in B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

In addition, a SBC must negotiate a written agreement between the small business and the research institution allocating intellectual property rights to carry out follow-on research, development, or commercialization. See the STTR Model Agreement for the Allocation of Rights. This agreement is required to receive support under the STTR program but is NOT submitted with the application. A copy of the Agreement must be furnished upon request of the NIH awarding component.

SBIR/STTR

An SBC may subcontract a portion of its SBIR or STTR award to a federal laboratory within the limits above. A federal laboratory, as defined in 15 U.S.C. § 3703, means any laboratory, any federally funded research and development center, or any center established under 15 U.S.C. §§ 3705 & 3707 that is owned, leased, or otherwise used by a federal agency and funded by the Federal Government, whether operated by the Government or by a contractor. An SBC may subcontract a portion of its STTR award to a Federally Funded Research and Development Center (FFRDC), either in its capacity as the Research Institution or as a participant in the STTR project in another capacity. **However, STTR funds may not be used to pay for laboratory resources of non-FFRDCs, and no STTR funds may be used to pay for subcontracting any portion of the STTR award back to the issuing agency or to any other federal government unit unless a waiver is granted by the Small Business Administration.**

A fee cannot be entered for a subaward/consortium budget. A fee is allowable only for the SBC budget page.

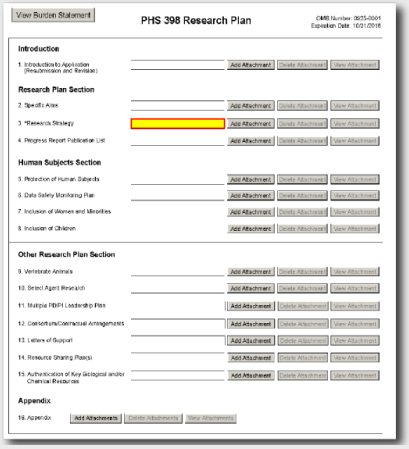
STTR only: If more than one subaward is included in the STTR application, identify the single, partnering research institution (RI) on the RI Subaward Budget Justification page.

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



View larger image

Quick Links

- Introduction
- Research Plan Section
- Human Subjects Section
- Other Research Plan Section
- Appendix

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 FOA. 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 FOA 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.

Additional Instructions for SBIR/STTR:

You are strongly encouraged to contact agency program staff for pre-application guidance and/or for more specific information on the research topics described in the solicitation.

The applicant small business must not propose market research, patent applications, or litigation. The research proposed in this application may, however,

be carried out through construction and evaluation of a laboratory prototype, where necessary.

Note to all Commercialization Readiness Pilot (CRP) Program Applications: CRP uses SBIR funding, but is not a Phase I/II/IIB or Fast-Track application. However, CRP applications should follow all Phase II-specific instructions.

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

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

Introduction

1. Introduction to Application (Resubmission and Revision)

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 FOA specifies that one is needed. An introduction is not allowed for new or renewal applications.

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

Format:

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

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

Content:

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

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

Research Plan Section

2. Specific Aims

Who must complete the "Specific Aims" attachment:

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

Format:

Follow the page limits for the Specific Aims in the NIH Table of Page Limits unless otherwise specified in the FOA.

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

Content:

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 SBIR/STTR:

Phase I Applications: State the specific objectives of the Phase I research and development effort, including the technical questions you will try to answer to determine the Phase I feasibility of the proposed approach and the impact that the results of the proposed research will exert on the research field(s) involved. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process or service to ultimately be developed. Include milestones for each of the aims as these will be used in the evaluation process.

Phase II, Phase IIB, and CRP Applications: State the specific objectives of the Phase II research and development effort including the impact that the results of the proposed research will exert on the research field(s). State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process or service to ultimately be developed. Include milestones for each of the aims as these will be used in the evaluation process.

Fast-Track Applications: Create a heading titled “Phase I Specific Aims” and follow the instructions above for “Phase I Applications.” Next, create a heading titled “Phase II Specific Aims” and follow the instructions above for “Phase II Applications.” Note that the page limit applies to both phases in combination, not to each phase individually.

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 FOA. Although multiple sections of information are required in the Research Strategy as detailed below, the page limit applies to the entirety of the single "Research Strategy" attachment.

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

Content:

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

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

1. Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Additional Instructions for SBIR/STTR:

Explain the project's potential to lead to a marketable product, process, or service.

Phase II, CRP, Fast-Track, and Phase IIB Competing Renewals: Explain how the commercialization plan demonstrates a high probability of commercialization.

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 the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- 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 further consideration of NIH expectations about sex as a biological variable.
- If your study(s) involves human subjects, the sections on Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample, but it must also be addressed here in the "Approach" section of the "Research Strategy" attachment.
- 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.

Additional Instructions for SBIR/STTR:

Provide a tentative sequence or timetable for the project.

If you have 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.

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.

Additional Instructions for SBIR/STTR:

Phase I Applications: Preliminary data are not required for Phase I Applications; however, such results may assist reviewers in assessing the likelihood of success of the proposed project and may be included in the Research Strategy attachment.

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, particularly if relevant to studies proposed in the renewal or revision application. You should not submit a PHS Inclusion Enrollment Report unless the enrollment is part of new or ongoing studies in the renewal or revision 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.

Additional Instructions for SBIR/STTR:

Phase II, Phase IIB, and CRP Competing Renewal and Revision Applications: In the Progress Report, in addition to what's listed above, describe the technology developed from this SBIR/STTR, its intended use, and who will use it. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).

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.

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

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.

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.

Additional Instructions for SBIR/STTR:

Phase II, Phase IIB, and CRP Applications: List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase I or describe patent status, trade secrets or other demonstration of IP protection, and other printed materials that have resulted from the Phase I effort.

Human Subjects Section

5. Protection of Human Subjects

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

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

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

Format:

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

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

Content:

Refer to Supplemental Instructions, Part II for instructions on this section. Additionally, be sure to follow any specific instructions in your FOA.

For more information:

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

6. Data Safety Monitoring Plan

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

Include a "Data Safety Monitoring Plan" attachment if you answered "Yes" to the question "Clinical Trial?" on B.210 - PHS 398 Cover Page Supplemental Form.

Format:

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

Content:

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

7. Inclusion of Women and Minorities

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

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

Format:

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

Content:

Refer to Supplemental Instructions, Part II, Section 4.2: Inclusion of Women and Minorities for instructions on this section.

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

8. Inclusion of Children

Who must complete the "Inclusion of Children" attachment:

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

Format:

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

Content:

Refer to the Supplemental Instructions, Part II (Section 4.4: Inclusion of Children and Section 5.8: NIH Policy on Inclusion of Children) for instructions on this section.

Other Research Plan Section

9. 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 B.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 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 vertebrate animals in the work outlined in the "Research Strategy" attachment. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. **Justifications:** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
3. **Minimization of Pain and Distress:** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Provide a concise, complete description of the animals and proposed procedures. In addition to the 3 points above, you should also:

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

See the following pages for more information:

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

10. Select Agent Research

Who must complete the "Select Agent Research" attachment:

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

Format:

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

For more information:

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. The Centers for Disease control and Prevention (CDC) and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See the Federal Select Agent Program website.

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

Content:

Excluded select agents: If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per

42 CFR 73.3, the select agent requirements do not apply. Use this "Select Agent Research" attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available on the Select Agents and Toxins Exclusions website.

Applying for a select agent to be excluded: If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

All applicants proposing to use select agents: Address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where select agent(s) will be used.
    - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.
    - *An "entity" is defined in 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.

11. Multiple PD/PI Leadership Plan

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

Any applicant who designates multiple PD/PIs (on the B.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 B.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.

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.

For more information:

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

12. 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 grantee.

Note: The signature of the authorized organization representative in B.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 SBIR/STTR:

SBIR:

Phase I Applications: Normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern (SBC). The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A/indirect, and fee).

Phase II and Phase IIB Applications: Normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the SBC. The total amount of consultant and contractual arrangements to third parties for portions of the

scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct, F&A/indirect, and fee).

Phase I and Phase II Applications: The basis for determining the percentage of work to be performed by each of the cooperative parties in Phase I or Phase II will be the total requested costs (direct, F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in this attachment.

Fast-Track SBIR Applications: Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements," and complete the sections following the instructions provided above for each phase.

Fast-Track SBIR Applications: Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements," and complete the sections following the instructions provided above for each phase.

STTR:

Phase I, Phase II and Phase IIB STTR Applications: At least 40% of the work must be performed by the SBC and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct, F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in this attachment.

Certification showing the cooperative R&D arrangement between the SBC and the research institution will be requested prior to an award.

The single partnering research institution must certify at the time of application that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution."

The requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution must be included in a letter stating:

> "The small business concern and the research institution certify jointly that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project.
>
> If the research institution is a contractor-operated Federally Funded Research and Development Center (FFRDC), the duly authorized representative of the

contractor-operated Federally funded research and development center certifies, additionally, that it: "(4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein."

The applicant SBC should convert the letter from the partnering research institution into a PDF attachment, and include it as part of this attachment.

Fast-Track STTR Applications: Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements," and complete the sections following the instructions provided above for each phase.

13. 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.

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.

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 (see exception for SBIR/STTR Applications in the SBIR/STTR-specific instructions).

Additional Instructions for SBIR/STTR:

Involvement of consultants and collaborators in the planning and research stages of the project is permitted. With the application, include letters from each individual and/or collaborator confirming their role(s) in the project. The letter(s) should be prepared on the consultant or collaborator's letterhead and addressed to the SBC. One page is recommended.

At a minimum, each consultant and collaborator letter should (1) verify their commitment to the project; (2) refer to the specific project by name, acknowledging

the PD/PI as the lead on the project; and (3) specify what services /tasks the consultant or collaborator will contribute (e.g. expertise, number of hours/ percent of effort, summary of tasks to be completed). For consultants, the letter should also include the rate/charge for consulting services. Also include biographical sketches for each consultant.

Letters of interest from potential commercial partners or investors and letters of commitment of funds or other resources that will enhance the likelihood of commercialization should be placed following the letters of support for consultants and collaborators.

STTR only: The single "partnering" research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution.

14. Resource Sharing Plan(s)

Format:

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

Content:

Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any budget period are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the FOA carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. **For more information**, see the NIH Data Sharing Policy or the NIH Guide Notice on Sharing Research Data.

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

Genomic Data Sharing (GDS): Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy. **For more information** see the NIH GDS Policy, the NIH Guide Notice on Genomic Data Sharing Policy, and the GDS website.

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

For more information:

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions, Part III, Section 1.5: Sharing Research Resources.

15. 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 be 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.
- See NIH Guide Notice on Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications for more information.

Appendix

16. Appendix

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

The appendix policy will be changing as of January 24, 2017. Please note that there are two sets of instructions below, based on the application due dates.

For applications submitted for due dates on or before January 24, 2017:

Format:

See NIH's Format Attachments page. A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining

information into attachment #10. Note that this is the total number of appendix items, not the total number of publications.

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

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

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

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

Applications that do not follow the appendix requirements will not be reviewed.

Content:

You **may** include the following items in the Appendix (note, however, that some FOAs do not permit publications):

- Publications are not allowed as appendix materials except in the circumstances noted below. When submitting an article, submit the entire article as a PDF attachment. Applicants may submit up to 3 of the following types of publications:
  - Manuscripts and/or abstracts accepted for publication but not yet published.
  - Published manuscripts and/or abstracts for which a free, online, publicly available journal link is not available.
- Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.
- Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix.

Do **not** include the following items in the Appendix:

- Unpublished theses or abstracts/manuscripts submitted (but not yet accepted) for publication.
- Digital photographs or color images of gels, micrographs, etc. (These images must be included in the Research Strategy PDF). However, images embedded in publications are allowed.
- Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers, along with the full reference, should be included as appropriate in the Bibliography and References Cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

Additional Instructions for SBIR/STTR:

Phase I SBIR/STTR Applications: Do not include appendices unless specifically solicited by NIH.

For applications submitted for due dates on or after January 25, 2017:

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 Appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications.

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

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

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

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

Content:

The only allowable appendix materials are:

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

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

For all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items
  - If appendix materials are required in the FOA, review criteria for that FOA will address those materials, and applications submitted without those Appendix materials will be considered incomplete and will not be reviewed.

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

For more Information:

- Information that expands upon or complements information provided in any section of the application – even if it is not required for the review – is not allowed in the Appendix unless it is listed in the allowed appendix materials above. For more information, see the NIH Guide Notice on Compliance with NIH Application Format and Content Instructions.
- Unless the FOA requires that certain information be included in the Appendix, failure of reviewers to address appendix materials in their reviews is not an acceptable basis for an

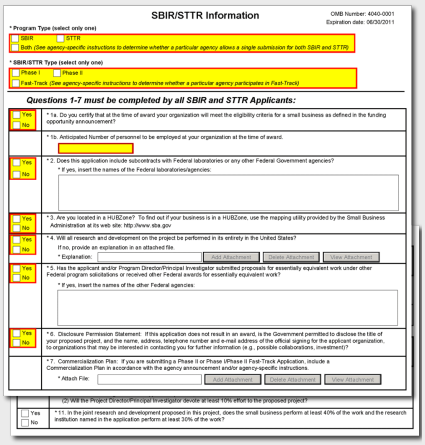
appeal of initial peer review. For more information, see the NIH Guide Notice on Appeals of NIH Initial Peer Review.

Additional Instructions for SBIR/STTR:

Phase I SBIR/STTR Applications: Do not include appendices unless specifically solicited by NIH.

B.440 - SBIR/STTR Information Form

NIH, CDC, FDA, and ACF SBIR/STTR grant applicants must complete and submit the SBIR/STTR Information Form in conjunction with the other SF424 (R&R) forms and PHS 398 forms.


SBIR/STTR Information

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

* Program Type (select only one)
SBIR STTR
Both (See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)

* SBIR/STTR Type (select only one)
Phase I Phase II
Fast-Track (See agency-specific instructions to determine whether a particular agency participates in Fast-Track)

Questions 1-7 must be completed by all SBIR and STTR Applicants:

Yes No * 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?

* 1b. Anticipated Number of personnel to be employed at your organization at the time of award.

Yes No * 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?
* If yes, insert the names of the Federal laboratories/agencies:

Yes No * 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov

Yes No * 4. Will all research and development on the project be performed in its entirety in the United States?
If no, provide an explanation in an attached file.
* Explanation: Add Attachment Delete Attachment View Attachment

Yes No * 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?
* If yes, insert the names of the other Federal agencies:

Yes No * 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborators, investment)?

* 7. Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.
* Attach File: Add Attachment Delete Attachment View Attachment

(2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?

Yes No * 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

View larger image

Quick Links

- Introductory Fields

1a. Certification of Small Business Eligibility

1b. Anticipated Number of personnel to be employed at your organization at the time of award

2. Subcontracts with Federal Government Agencies
3. Are You Located in a HUBzone?
4. Will All Research and Development on the Project be Performed in its Entirety in the United States?
5. Essentially Equivalent Work
6. Disclosure Permission Statement
7. Commercialization Plan
8. Have you Received SBIR Phase II Awards from the Federal Government?
9. Primary Employment of PD/PI at Time of Award
10. Commitment and Effort
11. Joint R&D

Who should use the SBIR/STTR Information Form:

All SBIR and STTR grant applicants must complete this form.

Introductory Fields

Program Type (select only one): SBIR/STTR/Both

A selection is required.

Check the correct box to indicate whether you are applying under the SBIR program or the STTR program. **Note:** HHS does not accept 'Both' as a choice.

SBIR/STTR Type (select only one): Phase I / Phase II / Fast-Track

A selection is required.

Check the correct box to indicate whether you are submitting a Phase I, Phase II, or Fast-Track Application.

Note: When submitting a Phase II Application following an awarded Phase I, please include the Phase I SBIR/STTR grant number in the "Federal Identifier" field on the B.200 – SF 424 (R&R) Form, Federal Identifier.

Questions 1-7 must be completed by all SBIR and STTR Applicants:

1a. Certification of Small Business Eligibility

A selection is required.

If you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the FOA, check "Yes." Otherwise, check "No."

1b. Anticipated Number of personnel to be employed at your organization at the time of award.

This information is required. Enter the number of personnel anticipated to be employed by the small business at the time of award.

2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?

A selection is required.

If this application includes subcontracts with federal laboratories or any other Federal Government agencies, check "Yes" and insert the name of the federal laboratories/agencies in the space provided. Otherwise, check "No."

3. Are you located in a HUBZone?

A selection is required.

If you are located in a HUBZone, check "Yes." Otherwise, check "No."

To find out whether your business is in a HUBZone, use the mapping utility provided on the Small Business Administration website.

4. Will all research and development on the project be performed in its entirety in the United States?

A selection is required.

If all research and development on the project will be performed in its entirety in the United States, check "Yes." Otherwise, check "No."

If you have answered "No" to this question, provide an explanation of the research and development that is being performed outside the United States in an "Explanation" attachment. Attach this information as a PDF file. See NIH's Format Attachments page.

5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?

A selection is required.

If the applicant and/or PD/PI has submitted proposals for essentially equivalent work under other federal program solicitations or received other federal awards for essentially equivalent work, check "Yes" and enter the names of the other federal agencies in the space provided. Otherwise, check "No."

6. Disclosure Permission Statement

A selection is required.

If this application does not result in an award, and the Government is permitted to disclose the title of your proposed project, and the name, address, telephone number, and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment), check "Yes." Otherwise check "No."

Your response will not affect any peer review or funding decisions.

7. Commercialization Plan

Who must complete the "Commercialization Plan" section:

If you are submitting a Phase II, Phase IIB, Phase I/Phase II Fast-Track, or Commercialization Readiness Pilot Program (CRP) Application, you must include a "Commercialization Plan" attachment.

Format:

Follow the page limits for the Commercialization Plan in the NIH Table of Page Limits unless otherwise specified in the FOA. You do not have to use the maximum number of pages allowed for your Commercialization Plan.

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

Content:

The Commercialization Plan must be written in accord with the solicitation and these instructions.

Organize your Commercialization Plan into six separate sections, following the headings and order below. Start each section with the appropriate heading – Value of the SBIR/STTR Project, Expected Outcomes, and Impact; Company; Market, Customer, and Competition; Intellectual Property Protection; Finance Plan; and Revenue Stream. Provide a description for each of the following areas:

a. Value of the SBIR/STTR Project, Expected Outcomes, and Impact

Describe, in layperson's terms, the proposed project and its key technology objectives. State the product, process, or service to be developed in Phase III. Clarify the need that is addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure

to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

b. Company

Give a brief description of your company, including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous federal and non-federal funding, regulatory experience, commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

c. Market, Customer, and Competition

Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market (e.g., better performance; lower cost; faster, more efficient or effective, new capability). Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.

Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product.

Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. A thorough understanding of the competition is essential to a successful application.

d. Intellectual Property (IP) Protection

Describe how you are going to protect the IP that results from your innovation. Also note other actions you may take that will constitute at least a temporal barrier against others aiming to provide a solution similar to yours.

e. Finance Plan

Describe the necessary financing you will require to commercialize the product, process, or service, and when it will be required. Describe your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

- Letter of commitment of funding.
- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
- Letter of support for the project and/or some in-kind commitment (e.g., to test or evaluate the innovation).
- Specific steps you are going to take to secure Phase III funding.

f. Production and Marketing Plan

Describe how the production of your product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/process/service. For example, explain plans for licensing, Internet sales, etc.

g. Revenue Stream

Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, and service. Describe how your staffing will change to meet your revenue expectations.

Your Phase III funding may be from any of a number of different sources, including, but not limited to:

- the SBIR/STTR firm itself;
- private investors or "angels;"
- venture capital firms;
- investment companies;
- joint ventures;
- R&D limited partnerships;
- strategic alliances;
- research contracts;
- sales of prototypes (built as part of this project);
- public offering;
- state finance programs;
- non SBIR-funded R&D or production commitments from a federal agency with the intention that the results will be used by the United States government; or
- other industrial firms.

Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Place any relevant letters in the B.400 - PHS 398 Research Plan Form, Letters of Support attachment, following letters from consultants and collaborators.

SBIR-Specific Questions

8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions.

A selection is required if you are submitting this application under the SBIR program.

If you have received SBIR Phase II awards from the Federal Government, check "Yes" and attach a statement or a company commercialization history in accordance with the instructions below. Attach this information as a PDF file. See NIH's Format Attachments page. Otherwise, check "No."

If the applicant small business has received an SBIR Phase II awards issued by NIH or any other Federal Government agency, attach a file that includes either:

(1) a statement indicating that the applicant small business has not received more than 15 SBIR Phase II awards from the Federal Government during the preceding five fiscal years; or

(2) a company commercialization history if the applicant small business has received more than 15 Phase II SBIR awards from the Federal Government during the preceding five fiscal years.

The company commercialization history must document the extent to which the company was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards.

For each Phase II award, the history must include: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award.

9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

A selection is required if you are submitting this application under the SBIR program.

If the PD/PI will have his/her primary employment with the small business at the time of award, check "Yes." Otherwise, check "No."

STTR-Specific Questions

10. Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?

A selection is required if you are submitting this application under the STTR program.

Check "Yes" if both of the following conditions are true:

1. The PD/PI has a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; and
2. The PD/PI will devote at least 10% effort to the proposed project.

Check "No" if either or both of these two conditions is false.

11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

A selection is required if you are submitting this application under the STTR program.

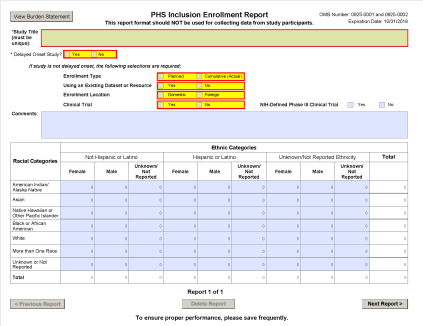
If in the joint research and development proposed in this project, the small business performs at least 40% of the work and the research institution named in the application performs at least 30% of the work, check "Yes." Otherwise, check "No."

B.500 - PHS Inclusion Enrollment Report

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

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

See below for form-specific instructions and refer to Supplemental Instructions, Part II Section 4.3: Instructions for Completing the PHS Inclusion Enrollment Report(s) for additional guidance on how and when to use the PHS Inclusion Enrollment Report.



View Burden Statement

PHS Inclusion Enrollment Report

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

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

*Study Title (must be unique)

* Delayed Onset Study? Yes No

If study is not delayed onset, the following selections are required

Enrollment Type: Planned Cumulative (Actual)

Using an Existing Dataset or Resource: Yes No

Enrollment Location: Domestic Foreign

Clinical Trial: Yes No

NIH-Defined Phase III Clinical Trial: Yes No

Comments:

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	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Report 1 of 1

< Previous Report | Delete Report | Next Report >

To ensure proper performance, please save frequently.

View larger image

Who should use the PHS Inclusion Enrollment Report?

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

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

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

Study Title (must be unique):

This field is required.

The Study Title can have a maximum of 250 characters.

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

Delayed Onset Study (Yes/No)?

This field is required.

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

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

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

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

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

Enrollment Type (Planned/Cumulative):

This field is required.

Select whether the enrollment table reflects:

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

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

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

This field is required.

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

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

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

Enrollment Location (Domestic/Foreign):

This field is required.

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

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

Clinical Trial (Yes/No):

This field is required.

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

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

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

This field is required.

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

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

Comments:

Your comments can have a maximum of 500 characters.

Enter information you wish to provide about this PHS Inclusion Enrollment Report. This includes, but is not limited to, addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied and/or a study that will have a delayed onset.

Racial Categories:

American Indian/Alaska Native:

These fields are required.

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

Asian:

These fields are required.

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

Native Hawaiian or Other Pacific Islander:

These fields are required.

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

Black or African American:

These fields are required.

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

White:

These fields are required.

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

More than One Race:

These fields are required.

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

Unknown or Not Reported:

These fields are required.

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

Total:

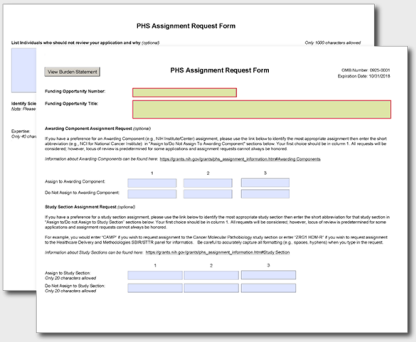
The total fields at the bottom will be automatically calculated and reflect the totals of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino and of all racial categories for females, males, and individuals of unknown/not reported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

B.600 - PHS Assignment Request Form

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

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

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


PHS Assignment Request Form

View larger image

Completing the PHS Assignment Request Form:

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

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

Awarding Component Assignment Request (optional)

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

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

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

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

Assign to Awarding Component:

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

Do Not Assign to Awarding Component:

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

Study Section Assignment Request (optional)

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

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

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

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

Assign to Study Section:

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

Do Not Assign to Study Section:

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

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

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

Your answer can have a maximum of 1000 characters.

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

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

Each field can have a maximum of 40 characters.

Form Screenshots

Quick Links

- SF 424 (R&R) Form
- PHS 398 Cover Page Supplement
- R&R Other Project Information Form
- Project/Performance Site Location(s) Form
- R&R Senior/Key Persons Profile (Expanded)
- R&R Budget Form
- R&R Subaward Budget Attachment(s) Form
- PHS 398 Research Plan
- SBIR/STTR Information Form
- PHS Inclusion Enrollment Report
- PHS Assignment Request Form

SF 424 (R&R) Form

OMB Number: 4040-0001

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE
State Application Identifier

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

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

2. DATE SUBMITTED
Applicant Identifier

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

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

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

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

8. TYPE OF APPLICATION:
☐ New ☐ Resubmission
☐ Renewal ☐ Continuation ☐ Revision

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

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

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

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

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

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

15. ESTIMATED PROJECT FUNDING

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

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

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

☐ **I agree**

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

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

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

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

Signature of Authorized Representative: Completed on submission to Grants.gov

Date Signed: Completed on submission to Grants.gov

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

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

PHS 398 Cover Page Supplement

PHS 398 Cover Page Supplement

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ☐ Yes ☐ No

*Agency-Defined Phase III Clinical Trial? ☐ Yes ☐ No

2. 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

3. *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)
X		

Add

4. 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: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

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

Cell Line(s) (Example: 0004):

X

Add

PHS 398 Cover Page Supplement

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: Yes ☐ No ☐

If "**Yes**" then answer the following:

*Previously Reported: Yes ☐ No ☐

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:
*First Name:
Middle Name:
*Last Name:
Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Other Project Information Form

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 6/30/2016

1. Are Human Subjects Involved? ☐ Yes ☐ No
   1.a. If YES to Human Subjects
   Is the Project Exempt from Federal regulations? ☐ Yes ☐ No
   If yes, check appropriate exemption number. ☐1 ☐2 ☐3 ☐4 ☐5 ☐6
   If no, is the IRB review Pending? ☐ Yes ☐ No
   IRB Approval Date:
   Human Subject Assurance Number:
2. Are Vertebrate Animals Used? ☐ Yes ☐ No
   2.a. If YES to Vertebrate Animals
   Is the IACUC review Pending? ☐ Yes ☐ No
   IACUC Approval Date:
   Animal Welfare Assurance Number:
3. Is proprietary/privileged information included in the application? ☐ Yes ☐ No
4.a. Does this Project Have an Actual or Potential Impact - 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

OMB Number: 4040-0010

Project/Performance Site Location(s)

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

Additional Location(s) Add Attachment Delete Attachment View Attachment

Senior/Key Persons Profile (Expanded)

OMB Number: 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

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

Credential, e.g., agency login:

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

Degree Type:
Degree Year:

***Attach 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

OMB Number: 4040-0001

ORGANIZATIONAL DUNS: **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:

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						

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 ($)

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.		
	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 ($)	Funds Requested ($)

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. Budget Justification

(Only attach one file.) Add Attachment Delete Attachment View Attachment

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		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

R&R Subaward Budget Attachment(s) Form

OMB Number: 4040-0001
Expiration Date: 6/30/2016

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the 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
11) Please attach Attachment 11		Add Attachment	Delete Attachment	View Attachment
12) Please attach Attachment 12		Add Attachment	Delete Attachment	View Attachment
13) Please attach Attachment 13		Add Attachment	Delete Attachment	View Attachment
14) Please attach Attachment 14		Add Attachment	Delete Attachment	View Attachment
15) Please attach Attachment 15		Add Attachment	Delete Attachment	View Attachment
16) Please attach Attachment 16		Add Attachment	Delete Attachment	View Attachment
17) Please attach Attachment 17		Add Attachment	Delete Attachment	View Attachment
18) Please attach Attachment 18		Add Attachment	Delete Attachment	View Attachment
19) Please attach Attachment 19		Add Attachment	Delete Attachment	View Attachment
20) Please attach Attachment 20		Add Attachment	Delete Attachment	View Attachment
21) Please attach Attachment 21		Add Attachment	Delete Attachment	View Attachment
22) Please attach Attachment 22		Add Attachment	Delete Attachment	View Attachment
23) Please attach Attachment 23		Add Attachment	Delete Attachment	View Attachment
24) Please attach Attachment 24		Add Attachment	Delete Attachment	View Attachment
25) Please attach Attachment 25		Add Attachment	Delete Attachment	View Attachment
26) Please attach Attachment 26		Add Attachment	Delete Attachment	View Attachment
27) Please attach Attachment 27		Add Attachment	Delete Attachment	View Attachment
28) Please attach Attachment 28		Add Attachment	Delete Attachment	View Attachment
29) Please attach Attachment 29		Add Attachment	Delete Attachment	View Attachment
30) Please attach Attachment 30		Add Attachment	Delete Attachment	View Attachment

PHS 398 Research Plan

View Burden Statement

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction

1. Introduction to Application (Resubmission and Revision)		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

Human Subjects Section

5. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
6. Data Safety Monitoring Plan		Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
8. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment

Other Research Plan Section

9. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
10. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
11. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
12. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
13. Letters of Support		Add Attachment	Delete Attachment	View Attachment
14. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
15. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

Appendix

16. Appendix	Add Attachments	Delete Attachments	View Attachments

SBIR/STTR Information Form

SBIR/STTR Information

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

*** Program Type (select only one)**

☐ SBIR ☐ STTR
☐ Both *(See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)*

*** SBIR/STTR Type (select only one)**

☐ Phase I ☐ Phase II
☐ Fast-Track *(See agency-specific instructions to determine whether a particular agency participates in Fast-Track)*

Questions 1-7 must be completed by all SBIR and STTR Applicants:

☐ Yes ☐ No	* 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award.
☐ Yes ☐ No	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? * If yes, insert the names of the Federal laboratories/agencies:
☐ Yes ☐ No	* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov
☐ Yes ☐ No	* 4. Will all research and development on the project be performed in its entirety in the United States? If no, provide an explanation in an attached file. * Explanation: Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? * If yes, insert the names of the other Federal agencies:
☐ Yes ☐ No	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?
	* 7. Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * Attach File: Add Attachment Delete Attachment View Attachment

SBIR/STTR Information

SBIR-Specific Questions:

Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

☐ Yes ☐ No	* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment. * Attach File: [ ] Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

STTR-Specific Questions:

Questions 10 and 11 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 and 11 blank.

☐ Yes ☐ No	* 10. Please indicate whether the answer to BOTH of the following questions is TRUE: (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND (2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?
☐ Yes ☐ No	* 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

PHS Inclusion Enrollment Report

View Burden Statement

PHS Inclusion Enrollment Report

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

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title (must be unique):**

* Delayed Onset Study? Yes No

If study is not delayed onset, the following selections are required:

Enrollment Type Planned Cumulative (Actual)

Using an Existing Dataset or Resource Yes No

Enrollment Location Domestic Foreign

Clinical Trial Yes No **NIH-Defined Phase III Clinical Trial** Yes No

Comments:

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

Report 1 of 1

< Previous Report | Delete Report | Next Report >

To ensure proper performance, please save frequently.

PHS Assignment Request Form

View Burden Statement

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

If you have a preference for an Awarding Component (e.g., NIH Institute/Center) assignment, please use the link below to identify the most appropriate assignment then enter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign To Awarding Component" sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

Information about Awarding Components can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#Awarding Components

	1	2	3
Assign to Awarding Component:			
Do Not Assign to Awarding Component:			

Study Section Assignment Request *(optional)*

If you have a preference for a study section assignment, please use the link below to identify the most appropriate study section then enter the short abbreviation for that study section in "Assign to/Do not Assign to Study Section" sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter "ZRG1 HDM-R" if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#Study Section

	1	2	3
Assign to Study Section: *Only 20 characters allowed*			
Do Not Assign to Study Section: *Only 20 characters allowed*			

PHS Assignment Request Form

List Individuals who should not review your application and why *(optional)* *Only 1000 characters allowed*

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

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