FORMS VERSION D SERIES

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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.

Quick Links

- Step 1. Become familiar with the application process
- Step 2. Select the correct application instructions.
- Step 3. Choose an Application Guide format.
- Step 4. Complete the appropriate forms.
- Step 5. Stay informed of policy changes and updates.

Step 1. Become familiar with the application submission process.

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

Step 2. Use these instructions together with the forms and information found in the funding opportunity announcement.

The funding opportunity announcement will include the forms needed for your application submission.

> **!** Remember that the funding opportunity announcement instructions always supersede these application instructions.

Step 3. Choose which application instruction format you prefer to use.

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)

Refer to the chart on Selecting the Correct Application Instructions to determine which set of application instructions applies to the type of grant program to which you are applying.

Step 4. Complete the appropriate forms.

For each field, follow the **standard instruction**, as well as, any additional **program-specific** instructions presented in the gray call out boxes. Program-specific instructions are color coded to simplify reviewing the document. Consult the Program Overview section for context for program specific instructions.

Step 5. Stay informed of policy changes and updates.

- Refer to the Significant Changes section for the most recent changes to these application instructions.
- Review changes to NIH policy 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 page limits and formatting requirements, information about due dates and submission policies, and more. 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

Understand Key Systems and Roles

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

https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/key-systems-and-roles.htm

Get Registered!

Determine your registration status. Organizations, organizational representatives, investigators, and others need to register in multiple federal systems in order to apply. Registration can take 6 weeks or more to complete. Start today!

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/registration.htm

Find and Understand Funding Opportunities

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

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/find-and-understand-foas.htm

Identify the Type of Application Submission

Are you submitting a new, renewal, revision, or resubmission application? Learn about special submission requirements for revisions and resubmissions.

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-application-submission.htm

Choose a Submission Option

Determine which system is most convenient for your submission to NIH: NIH's ASSIST on-line application submission system, Grants.gov downloadable forms, or your organization may have their own submission system.

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/choose-a-submission-option.htm

Obtain Software

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

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/obtain-software.htm

Format and Write

Write Your Application

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

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm

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.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm

Format Attachments

Follow these requirements for preparing the documents you attach to your application, including criteria for the pdf files, fonts, margins, headers and footers, paper size, citations, format pages and more.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

Refer to Table of Page Limits

Follow the page limits specified in this table unless instructed otherwise by the funding opportunity announcement to which you are applying.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/table-of-page-limits.htm

Utilize Biosketch, Data Tables and Other Format Pages

A comprehensive listing of the format pages you will use when you attach various files to your application, including instructions for submission of a reference letter.

Submission Process

Submit, Track and View Your Application

Learn how to submit your application to Grants.gov, and 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.

http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/submit-track-view.htm

Learn How We Check Your Application for Completeness

It is important that all applications being reviewed together adhere to the same rules. Consequently, your application will be checked at Grants.gov, by eRA systems and finally by federal staff before it is referred for review.

http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/check-your-application.htm

Submit a Changed/Corrected Application

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

http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/changed-corrected-application.htm

Submit a Reference letter

Some types of programs require the submission of reference letters by the referee. Referees must submit these letters by the application deadline in order to be considered as part of the application. Learn the process and policies for submission of reference letters.

http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letter.htm

Due Dates and Submission Deadlines

Due Dates

View standard due dates for NIH programs. The FOA will identify if a specific due date should be used.

http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm

Submission Policies

Learn the nuances of submission policies, including when we might allow late applications, 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, and more.

http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/application-submission-policies.htm

Guidelines for Applicants Experiencing System Issues

Experiencing system issues with ASSIST, Grants.gov, SAM, or NIH's eRA Commons that you believe threaten your ability to submit on time? NIH will not penalize applicants who experience confirmed issues beyond their control with federal systems. You must report the problem before the submission deadline.

http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/guidelines-for-applicants-experiencing-system-issues.htm

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 for possible funding.

http://grants.nih.gov/grants/receipt_referral.htm

Peer Review

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

http://grants.nih.gov/grants/peer_review_process.htm

Pre-Award Process

Learn what happens between peer review through award for applicants whose applications have been deemed highly meritorious in the scientific peer review process. Be ready, if you received a great score in peer review we will ask you to submit just-in-time information.

http://grants.nih.gov/grants/pre-award-process.htm

Post Award Monitoring and Reporting

If you are the recipient of a grant from the NIH, there is a great deal of information that you will need in order to be a successful steward of federal funds. This page provides a brief overview of grantee monitoring and reporting requirements.

http://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm

Resources

News - Items of Interest

The eSubmission Items of Interest provide comprehensive information on the changes impacting application development and submission in a friendly, informal format.

https://grants.nih.gov/grants/how-to-apply-application-guide/resources/news-items-of-interest.htm

Annotated Form Sets

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

http://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm

Contacting NIH Staff

NIH staff is here to help. We strongly encourage 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.

http://grants.nih.gov/grants/how-to-apply-application-guide/resources/contacting-nih-staff.htm

Contacting Staff at Other PHS Agencies

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

https://grants.nih.gov/grants/how-to-apply-application-guide/resources/contacting-staff-at-other-public-health-service-agencies.htm

Information Collection

Authorization

Describes NIH's statutory authorities for awarding grants.

http://grants.nih.gov/grants/authorization.htm

Paperwork Burden

Provides estimated time for completing a grant application.

http://grants.nih.gov/grants/paperwork-burden.htm

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.

http://grants.nih.gov/grants/collection-of-personal-demographic-data.htm

B.120 - Significant Changes

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

The section below denotes all changes and revisions made to the instructions since the last major release.

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 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-082.html)
- 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 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-080.html.

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.

New to SBIR/STTR?

View our SBIR/STTR Application Process Infographic.

Confirm Eligibility Requirements.

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 IC or HHS agency that is closely related to your research topic.

Five 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:

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	$150,000 total costs, 6 - 12 months	NIH, CDC, FDA, ACF	No	New/Resub

Application Name	Definition	Budget / Time Guidelines*	Participating HHS Component	Commercialization Plan?	Grant Type
	efforts				
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 Pilot Program (CRP)	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 to $3 million for up to 2-3 years	NIH, CDC	Yes	Renewal
Phase III	Commercialization activities (eg: Direct sales, partnerships, licensing deals, M&A)	N/A	Typically not supported by HHS	N/A	N/A

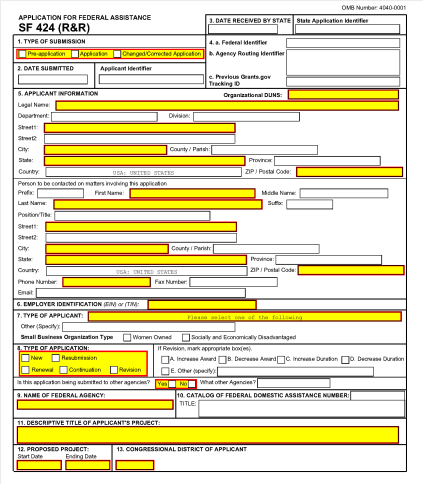
* At NIH, deviations from the budget guidelines are acceptable, but must be well justified and discussed with HHS program staff prior to submission. According to statutory guidelines, total funding support (direct costs, indirect costs, and fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. 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 at https://sbir.nih.gov/funding#omni-sbir. 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.

Additional SBIR/STTR instructions will be denoted by a purple box and “Additional Instructions for SBIR/STTR” heading.

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 (CFDA) Number and Title
11. Descriptive Title of Applicant's Project
12. Proposed Project
13. Congressional District of Applicant
14. Program Director/Principal Investigator (PD/PI) 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:

Unless specifically noted in a Funding Opportunity Announcement, the Pre-application option is not used by NIH and other PHS agencies.

Changed/Corrected Application:

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

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

Additional Instructions for SBIR/STTR:

SBIR/STTR Phase II applications may be submitted either before or after expiration of the Phase I budget period. However, Phase II grant applications should be submitted no later than the first six submission dates following expiration of the Phase I budget period.

Applicant small business concerns are reminded that Phase II funding is based on the results of Phase I, demonstration of feasibility, scientific, and technical merit, and commercial potential of the Phase II application. Applicants are cautioned that applications demonstrating insufficient results in Phase I may not receive a score in the peer review process.

2. Date Submitted and Applicant Identifier

The Applicant Identifier field is a control number created by the applicant organization, not the Federal agency.

3. Date Received by State and State Application Identifier

For submissions to NIH and other PHS agencies, leave these fields blank.

4.a. Federal Identifier

When a New Application is being submitted following a Pre-Application, enter the agency-assigned pre-application number, if applicable. If this is a continuation, revision, or renewal application, enter the assigned Federal Identifier number (for example, award number)--even if submitting a Changed/Corrected application.

For submissions to NIH and other PHS agencies, include only the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1). The Federal Identifier is required for Resubmission, Renewal, and Revision applications.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a “New” application, this field should remain blank.

Additional Instructions for SBIR/STTR:

To assist Phase I SBIR contractors or Phase I SBIR/STTR awardees from other agencies applying for SBIR/STTR Phase II or Phase IIB awards, resources are available on the web at: https://sbir.nih.gov/faqs#app-prep-sub26

4.b. Agency Routing Identifier

Unless specifically noted in a program announcement, the Agency Routing Identifier is not used by NIH or other PHS agencies.

4.c. Previous Grants.gov Tracking ID

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

5. Applicant Information

This information is for the Applicant Organization, not a specific individual.

Organizational DUNS:

Enter the DUNS or DUNS+4 number of the applicant organization. This field is required.

For submission to NIH and other PHS agencies, this DUNS must match the number entered in the eRA Commons Institutional Profile for the applicant organization. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile (IPF) prior to submitting an application. If your organization does not already have a DUNS number, you will need to go to the Dun & Bradstreet website at http://fedgov.dnb.com/webform

to obtain the number. The same DUNS should be used in the eRA Commons IPF, Grants.gov, System for Award Management (SAM) registration and in the DUNS field in the application.

Legal Name:

Enter the legal name of the applicant which will undertake the assistance activity, enter the complete address of the applicant (including county/parish and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application.

Department:

Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.

Division:

Enter the name of the primary organizational division, office, or major subdivision which will undertake the assistance activity.

Street1:

Enter the first line of the street address for the applicant in “Street1” field. This field is required.

Street2:

Enter the second line of the street address for the applicant in the “Street2” field. This field is optional.

City:

Enter the City for address of the applicant. This field is required.

County/Parish:

Enter the county/parish for address of the applicant.

State:

Enter the State where the applicant is located. This field is required if the applicant is located in the United States.

Province:

Enter the province. If “Country” is not Canada, please leave blank.

Country:

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

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.

Additional Instructions for SBIR/STTR:

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

For SBIR/STTR applications, the small business concern must be located in the United States.

Person to be contacted on matters involving this application:

This information is for the Administrative 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. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in the eRA Commons.

Prefix:

Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the person to contact on matters related to this application.

First Name:

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

Middle Name:

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

Last Name:

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

Suffix:

Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.

Position/Title:

Enter the Position/Title for the person to contact on matters related to this application.

Street1:

Enter first line of the street address for the person to contact on matters related to this application in the “Street1” field. This field is required.

Street2:

Enter the second line of the street address for the person to contact on matters related to this application in the “Street2” field. This field is optional.

City:

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

County/Parish:

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

State:

Enter the State where the person to contact on matters related to this application is located. This field is required if the applicant is located in the United States.

Province:

Enter the province for the person to contact on matters related to this application. If “Country” is not Canada, please leave blank

Country:

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

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of the person to contact on matters related to this application. This field is required if the performance site location is in the United States.

Phone Number:

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

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.

6. Employer Identification

Enter either TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the U.S., enter 44-4444444.

If you have a 12-digit EIN established for grant awards from NIH or other PHS agencies, enter all 12 digits (e.g., 1123456789A1); this includes non-U.S. organizations. This field is required.

Additional Instructions for SBIR/STTR:

For SBIR/STTR applications, the small business must be located in the United States.

7. Type of Applicant

Select the appropriate applicant type code. For eligible Agencies of the Federal Government, select X: Other (specify), and then indicate the name of the appropriate Federal agency in the space below. For SBIR/STTR applicant organizations, select R. Small Business. If Small Business is selected as Type of Applicant, then note if the organization is Woman-owned and/or Socially and Economically Disadvantaged.

Other (Specify):

Complete only if “Other” is selected as the Type of Applicant.

Woman Owned:

Check if you are a woman-owned small business – a small business that is at least 51% owned by a woman or women, who also control and operate it.

Socially and Economically Disadvantaged:

Check if you are a socially and economically disadvantaged small business, as determined by the U.S. Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).

Additional Instructions for SBIR/STTR:

For SBIR/STTR applicant organizations, select R. Small Business.

The applicant organization must certify that it will qualify as a small business concern at the time of award.

8. Type of Application

Select the type from the following list of existing definitions for NIH and other PHS agencies. Check only one. This field is required.

- ***New.*** Check this option when submitting an application for the first time or in accordance with other submission policies. See NOT-OD-14-074.
- ***Resubmission.*** Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH Policy on Resubmission Applications.
- **Renewal.** An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time.
- ***Continuation.*** For the purposes of NIH and other PHS agencies, the box for Continuation is only used for specific FOAs.
- ***Revision.*** For competing revisions and non-competing administrative supplements.

This field also affects how you complete the Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank unless otherwise specified in the funding opportunity announcement.

If “Type of Application” is “Renewal,” “Revision,” or “Resubmission,” enter the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1).

If Revision, mark appropriate box(es). May select more than one:

1. Increase Award
2. Decrease Award
3. Increase Duration
4. Decrease Duration
5. Other

If “Other” is selected, please specify in the text box provided.

For the purposes of NIH and other PHS agencies, 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?

In the field “Is this application being submitted to other agencies?,” please check the box “yes” if one or more of the specific aims submitted in your application are also contained in a similar, identical, or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted. For additional information,

please see NIH Guide Notice NOT-OD-09-100, *Reminder and Clarification of NIH Policies on Similar, Identical, or Essentially Identical Applications, Submission of Applications Following RFA Review, and Submission of Applications with a Changed Activity Code* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html. This field is required.

What Other Agencies?

Enter Agency Name

9. Name of Federal Agency

Name the Federal agency from which assistance is being requested with this application. This field is pre-populated from the opportunity package.

Additional Instructions for SBIR/STTR:

Name the Federal agency from which assistance is being requested with this application.

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

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

This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant's Project

Enter a brief descriptive title of the project. This field is required.

A "new" application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

A "revision" application must have the same title as the currently funded grant.

NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation.

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:

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

Ending Date:

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

Additional Instructions for SBIR/STTR:

Phase I: Routinely, SBIR Phase I awards do not exceed six (6) months and STTR Phase I awards do not exceed one year.

Phase II: Routinely, 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 that deviate from the guidelines 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 in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.

If outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site.

For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

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

If submitting an application reflecting Multiple PD/PIs, the individual designated as the Contact PI must be affiliated in the Commons with the applicant organization should be entered here. See Section B.240 - Senior/Key Person Profile (Expanded) Form for additional instructions for Multiple PD/PIs. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the PD/PI profile information contained in the eRA Commons.

Prefix:

The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.

First Name:

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

Middle Name:

Enter the middle name of the PD/PI.

Last Name:

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

Suffix:

Enter the suffix (e.g., Jr., Sr.) of the PD/PI. Do not use this field to record degrees (e.g., Ph.D.). Degrees for the PD/PI are requested separately in the Senior/Key Person Profile.

Position/Title:

Enter the Position/Title of the PD/PI.

Organization Name:

Enter the name of organization for the PD/PI. This field is required.

Department:

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

Division:

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

Street1:

Enter first line of the street address for the PD/PI in the “Street1” field. This field is required.

Street2:

Enter the second line of the street address for the PD/PI in the “Street2” field. This field is optional.

City:

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

County/Parish:

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

State:

Enter the State where the PD/PI is located. This field is required if the PD/PI is located in the United States.

Province:

Enter the province for PD/PI. If “Country” is not Canada, please leave blank

Country:

Select the country for the PD/PI address.

ZIP/Postal Code:

Enter the postal code (e.g., ZIP code) of the PD/PI. A nine-digit ZIP Code is required.

Phone Number:

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

Fax Number:

Enter the fax number for the PD/PI.

E-mail:

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

Additional Instructions for SBIR/STTR:

Name the one person responsible to the applicant small business concern for the scientific and technical direction of the project if a single PD/PI application, or the contact PD/PI for a multiple PD/PI application. PHS staff conduct official business only with the named PD/PIs and organizational/institutional officials. A revision/supplemental application must have the same PD/PI as the currently funded grant.

SBIR

Under the SBIR program, for both Phase I and Phase II, the primary employment of the PD/PI must be with the small business concern 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 small business concern. Primary employment with a small business concern 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 Multiple PD/PI applications: The first PI listed must be affiliated with the applicant small business concern organization submitting the application and will serve as the contact PD/PI. For both SBIR Phase I and SBIR Phase II, the primary employment of the "Contact PD/PI" must be with the small business concern 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.

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.

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 is a less-than-full-time employee of the small business concern, is concurrently employed by another organization, or 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 a 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 small business concern, 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

For both 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 principal investigator's time is spent in the employ of the SBC or the research institution. This precludes full-time employment with another organization aside from the SBC or the research institution. 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.

The PD/PI must commit a minimum of 10% (1.2 calendar months) effort to the project and the PD/PI must have a formal appointment with or commitment to the applicant small business concern, which is characterized by an official relationship between the small business concern 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. Documentation (e.g., consortium and contractual arrangements) describing the official relationship of the PD/PI with the applicant small business concern should NOT be submitted with the grant application, but a copy must be furnished upon the request of the NIH awarding component.

For Multiple PD/PI applications: The first PD/PI listed must be affiliated with the applicant small business concern and will serve as the Contact PD/PI. For STTR, 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.

Following is guidance for such documentation, which is required prior to award: The letter should be prepared on the letterhead of the independent PD/PI and addressed to the Small Business Concern (SBC). One page is recommended. At a minimum, each 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 of 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 for the project to continue to move forward (e.g., intellectual property).

Signatures of the Authorized Organization Representative (a.k.a. Signing Official) for the applicant organization on the Authorized Representative section form 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 small business concern when the PD/PI is an employee of the Research Institute (RI).

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 a routine basis. The PD/PI's commitment to the university and other organizations (including the applicant small business concern) cannot exceed 100% of his or her total professional effort.
- PD/PI with a full-time, 12-month appointment with a small business concern 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 a small business concern 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.

15. Estimated Project Funding

a. Total Federal Funds Requested

Enter total Federal funds requested for the entire project period. This field is required.

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 announcement. This field is required.

c. Total Federal & Non-Federal Funds

For NIH and other PHS agencies applicants, this field will be the same as Total Federal Funds Requested above unless the specific announcement indicates that cost sharing is a requirement. This field is required.

d. Estimated Program Income

Identify any Program Income estimated for this project period, if applicable. This field is required.

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

For NIH and other PHS agencies submissions using the SF424 (R&R), applicants should check "No, Program is not covered by E.O. 12372."

17. Certification

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

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

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

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

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

If unable to certify compliance in with the Certification above attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities) or other documents in this item. A fillable version of the SFLLL form is available at http://www.whitehouse.gov/omb/assets/omb/grants/sflllin.pdf.

19. Authorized Representative

This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organization Representative or the Signing Official.

Prefix:

Enter the prefix (Mr., Mrs., Rev.) for the name of the Authorized Representative.

First Name:

Enter the first (given) name of the Authorized Representative. This field is required.

Middle Name:

Enter the middle name of the Authorized Representative.

Last Name:

Enter the last (family) name of the Authorized Representative. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr., Ph.D.) for the Authorized Representative.

Position/Title:

Enter the Title of the name of the Authorized Representative. This field is required.

Organization Name:

Enter the name of the organization for the Authorized Representative. This field is required.

Department:

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

Division:

Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.

Street1:

Enter the first line of the street address for the Authorized Representative in the “Street1” field. This field is required.

Street2:

Enter the second line of the street address for the Authorized Representative in the “Street2” field. This field is optional.

City:

City for address of the Authorized Representative. This field is required.

County/Parish:

Enter the county/parish for address of the Authorized Representative.

State:

Enter the State where the Authorized Representative is located. This field is required if the Authorized Representative is located in the United States.

Province:

Enter the province for the Authorized Representative. If “Country” is not Canada, please leave blank.

Country:

Select the country for the Authorized Representative address.

ZIP/Postal Code:

Enter Postal Code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States. A nine-digit Zip code is required.

Phone Number:

Enter the daytime phone number for the Authorized Representative. This field is required.

Fax Number:

Enter the fax number for the Authorized Representative.

E-mail:

Enter the e-mail address for the Authorized Representative. This field is required.

Signature of Authorized Representative:

It is the organization’s responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If this application is submitted through Grants.gov, leave blank. If a hard copy is submitted, the AOR must sign this block.

Date Signed:

If this application is submitted through Grants.gov, the system will generate this date. If submitting a hard copy, enter the date the AOR signed the application.

20. Pre-Application

Unless specifically noted in a Funding Opportunity Announcement, NIH and other PHS agencies do not use Pre-applications and this attachment field should not be used for any other purpose.

If submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions, and save the file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

21. Cover Letter Attachment

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

Applicants are encouraged to include a cover letter with the competing application. Please attach the cover letter in the correct location, **specifically verify that the cover letter has not been uploaded to the pre-application field which is directly above the cover letter field**. This will ensure the

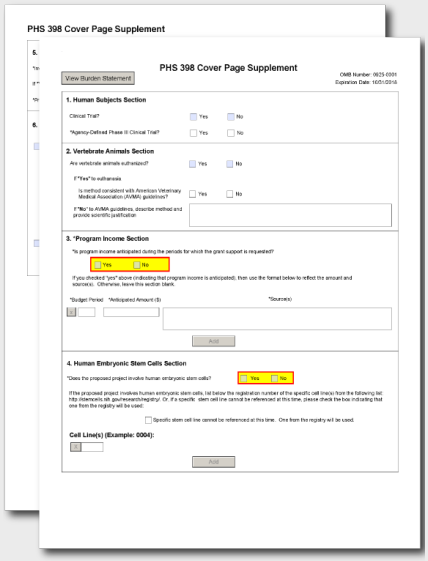
attachment is kept separate from the assembled application in Commons and only made available to appropriate staff.

A cover letter should not be included with post-award submissions such as administrative supplements, change of grantee institution, or successor-in-interest. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. For late applications (see Late Application policy in http://grants.nih.gov/grants/funding/submissionpolicies.htm) include specific information about the timing and nature of the cause of the delay.
4. When submitting a Changed/Corrected Application after the due date, a cover letter is required explaining the reason for late submission of the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a late Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
5. Explanation of any subaward budget components that are not active for all periods of the proposed grant Section B.240 - Senior/Key Person Profile (Expanded) Form.
6. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications $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.
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, a video will not be accepted. See NOT-OD-12-141 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 (NOT-OD-14-11 and NOT-OD-15-027.)

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 change 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 (For renewal applications only)
6. Change of Investigator/Change of Institution Section

1. Human Subjects Section

Clinical Trial?

Check "yes" or "no" to indicate whether the project includes a clinical trial. See Supplemental Instructions, Part III Section 3 for the specific definition.

Agency-Defined Phase III Clinical Trial:

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

An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included.

2. Vertebrate Animals Section

Are animals euthanized?

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

If "Yes" to euthanasia: Is method consistent with AVMA guidelines?

Check "Yes" or "No" to indicate whether the method of euthanasia is consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. See https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx for more information.

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

If you answered "No" to the question "Is method consistent with AVMA guidelines?" describe the method of euthanasia and provide a scientific justification for its use. If you answered "Yes", leave the section blank.

3. Program Income Section

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

If program income is anticipated during the periods for which the grant support is requested, check "Yes," and then complete the section below. If no program income is anticipated, check "No" and leave the following section blank.

Budget Period:

If program income is anticipated, enter the budget periods in this column. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.

Anticipated Amount ($):

If program income is anticipated, enter the amount anticipated for each budget period listed.

Source(s):

If program income is anticipated, enter the source for each budget period listed.

4. Human Embryonic Stem Cells Section

Does the proposed project involve human embryonic stem cells?

If the proposed project involves human embryonic stem cells, check Yes and complete the section below. If the proposed project does not involve human embryonic stem cells, check No.

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

If a specific line cannot be referenced at the time of application submission, check this box. Additionally, provide a strong justification for why an appropriate cell line is not available from the Registry at this time. The justification should be included as part of the Research Strategy or Program Plan as appropriate.

Cell Line(s):

List in this section the 4-digit registration number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry (e.g. 0123).

5. Inventions and Patents Section (For renewal applications only)

Inventions and Patents:

This block need only be completed if submitting an R&R “Renewal” application or a Resubmission of a Renewal application. If no inventions were conceived or reduced to practice during the course of work under this project, check “No.” The remaining parts of the item are then not applicable. If any inventions were conceived or first actually reduced to practice during the previous period of support, check “Yes.”

Note: 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, Bethesda, MD 20892-2750, (301) 435-1986. Invention reporting compliance according to regulations at 37 CFR 401.14 is described at http://www.iedison.gov. The grantee is required to submit reports electronically using Interagency Edison (http://www.iedison.gov). See NOT-OD-15-080.

Previously Reported:

If the item above is checked "Yes", indicate whether this information has been reported previously to the PHS 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 here, if this application reflects a change in principal investigator/program director from that indicated on a previous application. This is not generally applicable to a "New" application. For a multiple PD/PI application, check here if this application represents a change in the Contact PI.

Prefix:

If this application reflects a change in PD/PI, enter the name prefix (for example, Mr., Mrs., Rev.) of the former PD/PI.

First Name:

If this application reflects a change in PD/PI, enter the first name of the former PD/PI.

Middle Name:

If this application reflects a change in PD/PI, enter the middle name of the former PD/PI.

Last Name:

If this application reflects a change in PD/PI, enter the last name of the former PD/PI.

Suffix:

If this application reflects a change in PD/PI, provide the suffix (for example, Jr., Sr., PhD) of the former PD/PI.

Change of Grantee Institution:

Check here, if this application reflects a change in grantee institution from that indicated on a previous application. This is not generally applicable to a "New" application.

Name of Former Institution:

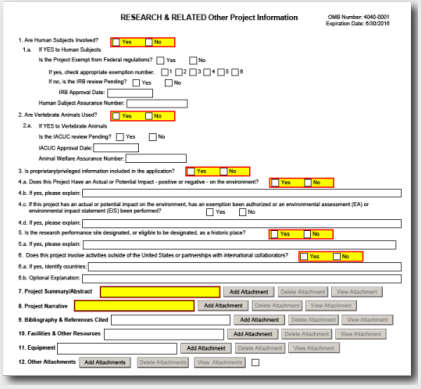
If this application reflects a change in grantee institution, insert the name of the former institution here.

Additional Instructions for SBIR/STTR:

Attach a relinquishing letter from the previous applicant institution as part of the Cover Letter.

B.220 - R&R Other Project Information Form

The Other Project Information Form is used for all grant applications. This form includes questions on the use of human subjects and vertebrate animals, as well as fields to upload an abstract, project narrative, references, equipment lists, and facilities descriptions.


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?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check Yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no and skip the rest of block 1. This field is required.

Note that applications involving the use of human biospecimens or data may or may not be considered as 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.

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? Yes/No

Yes: If the project is exempt from Federal regulations, check Yes. If yes, check the appropriate exemption number.

No: If the project is not exempt from Federal regulations, check No.

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

Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

Proposed research may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Human subjects research should be designated as exempt if all of the proposed research meets the criteria for one or more of the six exemptions.

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

If IRB review is pending, check Yes. If IRB review is not pending, check No.

IRB Approval Date:

Enter the latest Institutional Review Board (IRB) approval date (if available). Leave blank if Pending.

Applicants should check “Yes” to the question “Is the IRB review Pending?” even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle as a Supplemental Instructions, Part III Section 1.7 requirement.

Human Subject Assurance Number:

Enter the approved Federalwide Assurance (FWA) number that the applicant has on file with the Office for Human Research Protections. Enter the 8-digit number. Do not enter “FWA” before the number.

Insert “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 signature section on the SF424 (R&R) Cover form, is declaring that it will comply with 45 CFR part 46 and proceed to obtain a FWA (see http://www.hhs.gov/ohrp). Do not insert the FWA number of any collaborating institution in the space provided.

2. Are Vertebrate Animals Used?

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2. This field is required.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals. If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and add the Vertebrate Animals attachment to provide an explanation and to indicate when it is anticipated that animals will be used. If an award is made prior to the involvement of animals, the grantee must provide all of the information required by adding a Vertebrate Animals attachment in the Research Plan and verifying an IACUC approval to the awarding component.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending.

Click Yes if an IACUC review is pending. Click No, if no review is pending. Check “Yes” even if the IACUC review and approval process has not yet begun.

IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if Pending. IACUC approval must have been granted within three years to be valid. Note that an IACUC Approval Date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under Supplemental Instructions, Part III Section 1.7.

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available. Enter “None” if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. To determine if the applicant organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions. **Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution.** When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative’s signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

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

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: “The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.” This field is required.

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

4. Environmental Questions

Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer ‘No’ to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the box marked “Yes” should be checked and an explanation provided in field 4.b.

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

4.a. Does this project have an actual or potential impact on the environment?

Indicate if this project has an actual or potential impact on the environment? Click No here if this is not the case. This field is required.

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

Check yes or no. This field is required.

4.d. If yes, please explain

Enter additional details about the EA or EIS.

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

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes box and then provide an explanation in the box provided in 5.a. Otherwise, check the No box. This field is required.

5.a. If yes, please explain

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

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

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no. This field is required.

Applicants to NIH and other PHS agencies must check “Yes” if the applicant organization is a foreign institution or if the project includes a foreign component. For a definition of a foreign component, see “Definitions” section of Supplemental Instructions, Part III.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

6.b. Optional Explanation

Enter an explanation for involvement with outside entities (optional).

If you have checked “Yes” to 6, applicants to the NIH and other PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. Provide this information in a separate file,

attaching it as Item 12, Other Attachments. In the body of the text, begin the section with a heading indicating "Foreign Justification." When saving this file, please name it "Foreign Justification" as well.

7. Project Summary/Abstract

The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct.

This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at http://report.nih.gov) and will become public information.

The attachment must be in PDF format. (See Formatting Attachments for additional information on preparing attachments.)

8. Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the Add Attachment button to the right of this field to complete this entry.

For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to public health. 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.

A separate Research Plan form is required for NIH and other PHS agencies applications. Refer to Section B.400 - PHS 398 Research Plan Form, Research Plan for separate file uploads and instructions.

9. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only

bibliographic citations. To attach a document for Bibliography and References Cited, click **Add Attachment**.

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section should include any references cited in Section 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." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

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

10. Facilities & Other Resources

No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, 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; and financial support such as protected time for research with salary support. See http://grants.nih.gov/grants/new_investigators/.

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

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

Please click the **Add Attachment** button to the right of this field to complete this entry.

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 (i.e., foreign sites must be approved by the funding officer) that are available to and under the control of each party for the conduct of each party's portion of the proposed project.

11. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the **Add Attachment** button to the right of this field to complete this entry.

12. Other Attachments

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

Additional Instructions for SBIR/STTR:

SBA Company registry (for both SBIR and STTR):

All applicants to the SBIR and STTR programs are required to register at the SBA Company Registry prior to application submission and attach proof of registration. Completed registrations will receive a unique SBC Control ID and .pdf file. If applicants have previously registered, you are still required to attach proof of registration. The SBA Company Registry recommends verification with 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 these steps listed below to register and attach proof of registration to your application.

- 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.
- 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.
- When you are completing the application package, attach this SBA registry PDF as a separate file by clicking Add Attachments located to the right of Other Attachments on the “Research and Related Other Project Information” form.

For questions and for technical assistance concerning the SBA Company Registry, please contact the SBA at http://sbir.gov/feedback?type=reg.

NIH and CDC SBIR Only:

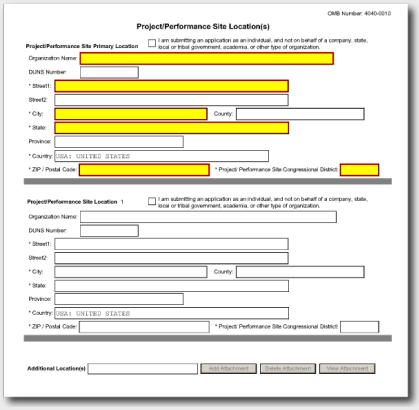
SBIR Application Certification for small business concerns majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms. Applicant small business concerns that are majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms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

Applicants small business concerns who 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 their application package.

- Download the “SBIR Application VCOC Certification.pdf” at the NIH SBIR Forms webpage.
- 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. The file must be named “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.

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

The Project/Performance Site Location(s) Form is used for all grant applications. Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided.



View larger image

Quick Links

1. Project/Performance Site Primary Location
2. Project/Performance Site Location 1
3. Additional Performance Site Locations

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.

If there is more than one performance site, including any Department of Veterans Affairs (VA) facilities and foreign sites, list them in the fields provided for Location 1 - # below. Applicants should also provide an explanation of resources available from each Project/Performance Site on the Facilities and Resources attachment of the Section B.220 - R&R Other Project Information form, and describe any consortium/contractual arrangements in Section B.400 - PHS 398 Research Plan, Consortium/Contractual Arrangements .

Unless otherwise instructed in the FOA, do not check the "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" box.

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 part 46 and other NIH human subject related policies described in Supplemental Instructions Part II of this Application Guide and in the NIH Grants Policy Statement.

Vertebrate Animals:

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold an OLAW-approved Animal Welfare Assurance. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

Additional Instructions for SBIR/STTR:

SBIR/STTR applications, one of the performance sites indicated must be that of the applicant small business concern.

For both Phase I and Phase II, 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 small business concern 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 small business concern (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 Section B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

Organization Name:

Indicate the organization name of the primary site where the work will be performed. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.

DUNS Number:

Enter the DUNS number associated with the organization where the project will be performed. The DUNS Number is a required field for the Primary Performance Site.

Street1:

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

Street2:

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

City:

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

County/Parish:

Enter the County or parish of the primary performance site location.

State:

Enter the State where the primary performance site location is located. This field is required if the Project Performance Site is located in the United States.

Province:

Enter the province for the primary performance site location. If “Country” is not Canada, please leave blank.

Country:

Select the Country of the Primary Performance Site location. This field is required.

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States. A nine-digit Zip code is required.

Project/Performance Site Congressional District:

Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.

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

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

If the program/project is outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site. Note it is likely this field will be identical to the “Congressional District of Applicant” field provided elsewhere in the application.

For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.

Project/Performance Site Location 1

Organization Name:

Enter the name of organization of the performance site location. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.

DUNS Number:

Enter the DUNS number associated with the organization where the project will be performed. This field is optional.

Street1:

Enter first line of the street address for the performance site location in the “Street1” field. This field is required.

Street2:

Enter the second line of the street address for the performance site location in the “Street2” field. This field is optional.

City:

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

County:

Enter the county of the performance site location.

State:

Enter the State where the primary performance site location is located. This field is required if the Project Performance Site is located in the United States.

Province:

Enter the province where the primary performance site location is located. If “Country” is not Canada, please leave blank.

Country:

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

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.

Project/Performance Site Congressional District:

Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.

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

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

If the program/project is outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site. Note it is likely this field will be identical to the “Congressional District of Applicant” field provided elsewhere in the application.

For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.

Additional Performance Site Locations

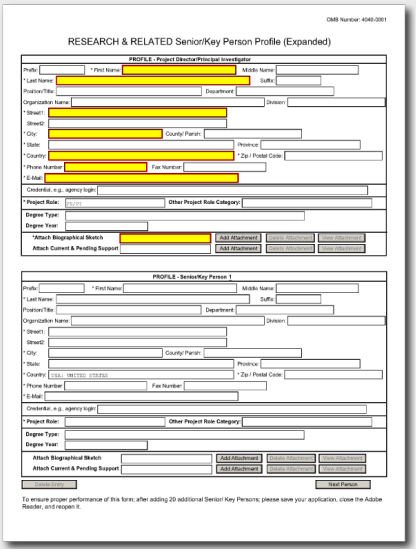
For additional performance site locations, click Next Site to display the fields for Project/Performance Site Locations 2 through 300.

If you need to add more than 300 locations, enter the information in a separate file. In the Additional Locations section at the bottom of the form, click Add Attachment, select the file, and then click Open. A sample Additional Performance Sites format page for greater than eight locations can be found at http://grants.nih.gov/grants/forms/additional-performance-site.htm.

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

The 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. The information for the PD/PI is pre-populated from the SF424 (R&R) form. See instructions in Section B.200 - SF 424 (R&R) Form if these fields are empty.

View larger image



Quick Links

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

Multiple PD/PIs (not applicable to Career Development or Fellowships Awards)

NIH accepts applications reflecting Multiple PD/PIs for all grant activity codes using the SF424 (R&R) application. When submitting an application involving Multiple PD/PIs, the Contact PD/PI must be affiliated in the Commons with the applicant organization and should be listed as the PD/PI in the SF424 R&R form (see Section B.200 - SF 424 (R&R) Form). That information automatically prepopulates the first senior/key person profile record in this form. For the additional PD/PIs, complete all the requested information. Each PD/PI must be assigned the PD/PI role, even those at subaward/consortium sites when applicable (do not use the “Co-PD/PI” or Co-Investigator role.). For more information, please see Section B.310 - R&R Subaward Budget Attachment(s) Form.

Each PD/PI must also be registered in the eRA Commons and must be assigned the PI Role in that system (note other roles such as SO or IAR will not give PD/PIs the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the Credential field. For more information on NIH Implementation of Multiple PD/PIs, see: http://grants.nih.gov/grants/multi_pi/index.htm.

When completing the detailed budget form for either the prime organization or a subaward/consortium organization, the project roles listed in the budget form should be consistent with those used in the Senior/Key Person Form.

Profile - Project Director/Principal Investigator (PD/PI)

Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

Data must be entered for the first 100 individuals (PD/PI + 99 others) before the Additional Senior/Key Person Form Attachments section becomes available.

Additional Instructions for SBIR/STTR:

Special Note for STTR applicants: The STTR applicant organization must officially affiliate the PD/PI with the small business concern in the Commons if the PD/PI is not an employee of the small business concern. For additional information on creating affiliations for users in the eRA Commons, see: https://era.nih.gov/commons/commons-help/175.htm.

Prefix:

Pre-populated from the SF 424 (R&R). The prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI

First Name:

Pre-populated from the SF 424 (R&R). The first (given) name of the PD/PI. This field is required.

Middle Name:

Pre-populated from the SF 424 (R&R). The middle name of the PD/PI.

Last Name:

Pre-populated from the SF 424 (R&R). The last (family) name of the PD/PI. This field is required.

Suffix:

Pre-populated from the SF 424 (R&R). The suffix (e.g., Jr, Sr, PhD) for the name of the PD/PI.

Position/Title:

Pre-populated from the SF 424 (R&R). The title of the PD/PI.

Department:

Pre-populated from the SF 424 (R&R). The name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.

Organization Name:

Pre-populated from the SF 424 (R&R). The name of organization of the PD/PI.

Division:

Pre-populated from the SF 424 (R&R). The name of primary organizational division, office, or major subdivision of the PD/PI.

Street1:

Pre-populated from the SF 424 (R&R). The first line of the street address for the PD/PI in the "Street 1" field. This field is required.

Street2:

Pre-populated from the SF 424 (R&R). The second line of the street address for the PD/PI in the "Street 2" field. This field is optional

City:

Pre-populated from the SF 424 (R&R). The city for address of PD/PI. This field is required.

County/Parish:

Pre-Populated from the DF 424 (R&R). The county/parish for address of PD/PI.

State:

Pre-populated from the SF 424 (R&R). The state where the PD/PI is located. This field is required if the PD/PI is located in the United States.

Province:

Pre-populated from the SF 424 (R&R). The Province where the PD/PI is located. If “Country” is not Canada, this will be blank.

Country:

Pre-populated from the SF 424 (R&R). The country for the PD/PI address. This field is required.

ZIP Code:

Pre-populated from the SF 424 (R&R). The postal Code (e.g., ZIP code) of PD/PI. This field is required if the PD/PI is located in the United States. A nine-digit Zip code is required.

Phone Number:

Pre-populated from the SF 424 (R&R). The daytime phone number for the PD/PI. This field is required.

Fax Number:

Pre-populated from the SF 424 (R&R). The fax number for the PD/PI.

E-mail:

Pre-populated from the SF 424 (R&R). The e-mail address for the PD/PI. This field is required for PD/PI.

Credential, e.g., agency login:

For NIH and other PHS agencies, registration in the eRA Commons for all PD/PIs is required. The assigned Commons username (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here and must have the PI role in eRA Commons. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.

Note for applications reflecting Multiple PD/PIs, the Commons username must be provided for all individuals assigned the PD/PI Role on the application.

Project Role:

Select PD/PI for this person.

Other Project Role Category:

Complete if you selected “Other Professional” or “Other” as a project role; e.g., Engineer, Chemist.

Degree Type:

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

Degree Year:

Enter the year the highest degree or other credential was obtained. This is optional information.

Attach Biographical Sketch

See instructions below

Attach Current & Pending Support:

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to Supplemental Instructions, Part III Section 1.8.

Instructions for a Biographical Sketch

Please note that these instructions apply to Research (R), Career Development (K), Training (T), Fellowship (F), Multi-Project (M) and SBIR/STTR (B).

- Include biographical sketches of all senior/key personnel and Other Significant Contributors.
- Use the sample format on the Biographical Sketch Format Page to prepare this section for all (modular and other) grant applications.
- The Biographical Sketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.
- Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral training, separately referencing residency and clinical fellowship training, if applicable.

eRA Commons User Name

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI (including fellowship applicants), primary sponsors of fellowship applicants, and all mentors of candidates for mentored career development awards. Commons User Name is optional for other project personnel. In other federal forms this information is referred to as “Credential, e.g., agency login.” For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.

Education

Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral training, separately referencing residency and clinical fellowship training, if applicable. For each entry provide:

- the name and location of the institution
- the degree received (if applicable) and the month and year of entry and completion (or expected completion)

- 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, B, C, and D as described below.

A. Personal Statement

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

- For institutional research training, institutional career development, or research education grant applications, faculty who are not senior/key persons are encouraged to complete this section, but not required to do so.
- Applicants for dissertation research awards should include a description of their career goals and intended career trajectory and their interest in the specific areas of research designated in the FOA, in addition to the information outlined above.
- Candidates for Research Supplements to Promote Diversity in Health-Related Research should include a description of their general scientific achievements and/or interests, as well as specific research objectives and career goals, in addition to the information outlined above. Indicate any current source(s) of educational funding.
- If there are factors affecting your past productivity that you wish to explain, such as family care responsibilities, illness, disability, or military service, you may address them in your personal statement.
- Indicate if 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 the application.
- Figures, tables and graphics are not allowed.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include 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.

B. Positions and Honors

List in chronological order positions held since the completion of your most recent degree, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals, such as fellowship applicants or career development award candidates, who are not currently located at the applicant organization, include the expected position at the applicant organization, with 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 clinical licensure and specialty board certification, if

applicable.

- Include present membership on any Federal Government public advisory committee.

C. Contributions to Science

Candidates for Research Supplements to Promote Diversity in Health-Related Research who are high school students, undergraduates, and postbaccalaureates are not required to complete this section.

Briefly describe up to five of your most significant contributions to science. While all applicants may describe up to five contributions, graduate students and postdoctorates are encouraged to consider highlighting two or three they consider most significant. Descriptions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication.

Each contribution should be no longer than one half page, including citations. These contributions do not have to be related to this project. For each contribution:

- Indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work.
- You may cite up to four papers accepted for publication or research products that are relevant to the contribution.
    - Research products can include 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.
    - These citations do not have to be authored by you.

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, and reviewers are not required to look at the list.

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

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

- High school students are not required to complete this section.
- Applicants for predoctoral and postdoctoral fellowships, dissertation research grants, and candidates for Research Supplements to Promote Diversity in Health-Related Research from the undergraduate through postdoctoral levels should use this section to provide information about their scholastic performance, following the instructions below. In situations where applicants/candidates in these categories also have research support, they should complete both parts of this section.

Research Support

For all other individuals required to complete a biosketch, list selected ongoing and completed research projects for the past three years (Federal or non-Federal support). Briefly indicate the overall goals of the projects and your responsibilities. Do not include number of person months or direct costs.

Do not confuse “Research Support” with “Other Support.” Though they sound similar, these parts of the application are very different.

- As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual’s qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.
- In contrast, “Other Support” information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date “other support” information from you after peer review.

Scholastic Performance

Predoctoral applicants/candidates (including undergraduates and postbaccalaureates): List by institution and year all undergraduate and graduate courses, with grades. In addition, in the space following the chart, explain any grading system if other than 1-100, A, B, C, D, F, or 0-4.0. Show levels required for a passing grade.

Postdoctoral applicants: List by institution and year all undergraduate courses and graduate scientific and/or professional courses germane to the training sought under this award, with grades. In the space following the chart, explain any grading system if other than 1-100, A, B, C, D, F, or 0-4.0. Show levels required for a passing grade.

Profile - Senior/Key Person

The remaining senior/key person profiles should be listed in alphabetical order. While alphabetical order is preferred, it is not required. However, be aware that these profiles will appear in the application in the order provided by the applicant. Therefore, peer reviewers will see them in the order presented. Those with a postdoctoral role should be included if they meet the definition of senior/key personnel.

Also use this section to list any Other Significant Contributors (OSCs), who are those individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at effort of “zero person months” or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet the OSC definition. OSCs should be listed **after** all senior/key persons.

A biosketch, including Research Support information, is required for all senior/key persons and OSCs as this highlights their accomplishments as scientists. Reviewers use these pages to address the “investigator” review criterion. However, if an award is to be made, 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 change for an individual listed as an OSC, requiring measurable effort on the award, the individual should be redesignated as “senior/key personnel.” This change should be made before any compensation is charged to the project.

After providing data for each individual senior/key person (the following instructions also apply to OSCs), click the **Next Person** button at the bottom of the form to enter data for the next senior/key person. Continue in this manner until data has been provided for up to 100 senior/key persons. To ensure proper performance of this form, after adding 20 additional senior/key persons please save

your application, close the Adobe reader, and reopen it. For applications involving more than 100 senior/key persons, the “Additional Senior/Key Person Profiles” fields will become available once data for the first 100 senior/key persons has been provided.

Prefix:

Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the Senior/Key Person.

First Name:

Enter the first (given) name of the Senior/Key Person. This field is required.

Middle Name:

Enter the middle name of the Senior/Key Person, if applicable.

Last Name:

Enter the last (family) name of the Senior/Key Person. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Senior/Key Person.

Position/Title:

Enter the title of the Senior/Key Person.

Department:

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

Organization Name:

Enter the name of organization of the Senior/Key Person. This is a required field for applications submitted to NIH and other PHS agencies.

Division:

Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person.

Street1:

Enter first line of the street address for the Senior/Key Person in the "Street 1" field. This field is required.

Street2:

Enter second line of the street address for the Senior/Key Person in the "Street 2" field. This field is optional.

City:

City for address of Senior/Key Person. This field is required.

County/Parish:

County/Parish for address of Senior/Key Person.

State:

Enter the State where the Senior/Key Person is located. This field is required if the senior/key person is located in the United States.

Province:

Enter the Province where the Senior/Key Person is located. If “Country” is not Canada, please leave blank.

Country:

Select the country for the Senior/Key Person address. This field is required.

ZIP Code:

Enter the Postal Code (e.g., ZIP code) of Senior/Key Person. This field is required if the Senior/Key Person is located in the United States. A nine-digit Zip code is required.

Phone Number:

Enter the daytime telephone number for the Senior/Key Person. This field is required.

Fax Number:

Enter the fax number for the Senior/Key Person.

E-mail:

Enter the e-mail address for the Senior/Key Person. This field is required for the Senior/Key Person.

Credential, e.g., agency login:

If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank.

Project Role:

Select one. Use "Other" if a category is not listed in the pick list.

For applications reflecting Multiple PD/PIs, all such individuals 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 and other PHS agencies. Assigning an individual(s) the role of "Co-PD/PI" will not identify the application as a Multiple PD/PI application. If applicants wish to use a different role, select “Other” for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field.

If including individuals classified as “Other Significant Contributors (OSCs),” use the “Other” category and indicate “Other Significant Contributor” as the role in the “Other Project Role Category.” OSCs should be listed last after all other senior/key persons have been listed.

Other Project Role Category:

Complete if you selected “Other Professional” or “Other” as a project role; e.g., Engineer, Chemist.

Degree Type:

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

Degree Year:

Enter the year the highest degree or other credential was obtained. This is optional information. Applicants should ensure that their degree information is current in their Commons Profile.

Attach Biographical Sketch:

Provide a biographical sketch for each senior/key person. Biographical sketches must follow the format described above.

Attach Current & Pending Support:

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs refer to Supplemental Instructions, Part III Section 1.8.

Additional Senior/Key Person Profile(s)

If more than 99 senior/key person profiles are proposed, enter the information in a separate file and attach it here. A sample Additional Senior/Key Person Profiles format page for greater than 100 profiles can be found at: http://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm.

Additional Biographical Sketch(es) (Senior/Key Person):

Provide a biographical sketch for each senior/key person. Biographical sketches must follow the format described above.

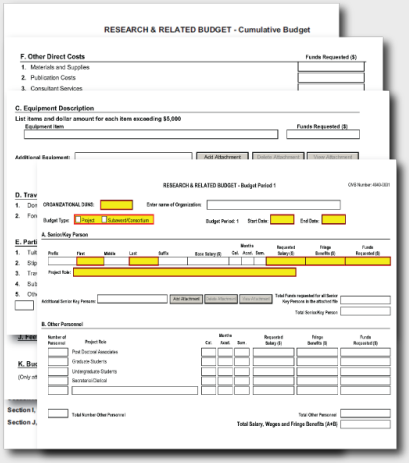
Additional Current and Pending Support(s):

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to Supplemental Instructions, Part III Section 1.8.

B.300 - R&R Budget Form

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

Some application forms packages include two optional budget forms—(1) R&R Budget Form; and, (2) PHS 398 Modular Budget Form. However, applications must include only one of these forms, but not both.



View larger image

Quick Links

- A. Senior/Key Person
- B. Other Personnel
- C. Equipment Description
- D. Travel
- E. Participant/Trainee Support Costs
- F. Other Direct Costs
- G. Total Direct Costs (A through F)
- H. Indirect Costs
- I. Total Direct and Indirect Institutional Costs (G + H)
- J. Fee
- K. Budget Justification
- Cumulative Budget

Using the R&R Budget Form:

The R&R Budget form includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through K. To navigate between the various screens, use the **Previous** and **Next** buttons at the top of the form or use the scroll bar on the side of the screen. Complete the R&R Budget form following the instructions provided. You must complete a separate detailed budget for each year of support requested. The form will generate a cumulative budget for the total project period. If no funds are requested for a required field, enter “0.”

While the dollar fields allow cents to be entered, all dollar fields should be presented in whole numbers. Please round to the nearest whole number.

Person Months:

NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at:

http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available.

Additional Budget Periods:

If funds are being requested for more than one budget period, click the Next Period button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.

Revision (Supplemental) Application:

For a Revision application, show only those items for which additional funds are requested. If the initial budget period of the Revision application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

Foreign Grantee Budget Guidelines:

All competing (new, renewal, resubmission, and revision) grant applications from foreign (non-U.S.) institutions must include only detailed (non-modular) budgets. For additional information, see NIH Guide Notice NOT-OD-06-096, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-096.html. Applications from foreign organizations must request budgets in U.S. dollars.

Introductory Fields

Organizational DUNS:

Enter the DUNS or DUNS+4 number of the applicant organization. For project applicant, this field is pre-populated from the SF 424 (R&R) form. For subaward applicants, this field is a required enterable field.

Enter name of Organization:

Pre-populated from the SF 424 (R&R) form. Enter the name of the organization.

Budget Type:

Project, Subaward/Consortium: Check the appropriate block. This field is required.

Project:

The budget requested for the primary applicant organization.

Subaward/Consortium:

The budget requested for subawardee/consortium organization(s). Note, separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

If creating Subaward Budget, use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form.

If you are preparing an application that includes a subaward/consortium, see Section B.310 - R&R Subaward Budget Attachment(s) Form.

Start Date:

Pre-populated from the SF424 (R&R). Enter the requested/proposed start date of each budget period. This field is required.

End Date:

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

Budget Period:

Identify the specific budget period (for example, 1, 2, 3, 4, 5). If submitting through Grants.gov, the system will automatically generate a cumulative budget for the total project period. This is a required field.

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the form.)

A. Senior/Key Person

This section should include the names of all senior/key persons at the applicant organization who are involved on the project in a particular budget year. Include all collaborating investigators, and other individuals meeting the senior/key person definition if they are from the applicant organization. Details of collaborators at other institutions 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 of the budget since no associated salary and/or fringe benefits should be requested for their contribution. Consultants designated as senior/key persons in the Senior/Key Person Profile Form can be included in Budget Section A only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in Consultant Services.

Prefix:

Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of each Senior/Key Person.

First Name:

Enter the first (given) name of each Senior/Key Person.

Middle Name:

Enter the middle name of each Senior/Key Person, if applicable.

Last Name:

Enter the last (family) name of each Senior/Key Person. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr., PhD) of each Senior/Key Person.

Base Salary ($):

Enter the annual compensation paid by the employer for each Senior/Key Person. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank. An applicant organization may choose to leave this blank; however, PHS staff will request this information prior to award.

Cal. Months:

Identify the number of months devoted to the project for each senior/key person (i.e., calendar, academic, summer). 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. Please use either calendar months OR a combination of academic and summer months. Some measurable effort is required for every Senior/Key Person entry.

Acad. Months:

Identify the number of months devoted to the project for each senior/key person (for example, calendar, academic, summer). If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification. Some measurable effort is required for every Senior/Key Person entry.

Sum. Months:

Identify the number of months devoted to the project for each senior/key person (for example, calendar, academic, summer). If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification. Some measurable effort is required for every Senior/Key Person entry.

Requested Salary ($):

Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each senior/key person. This field is required. 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 Salary Cap Summary on the NIH grants website or contact your office of sponsored programs.

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: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

Fringe Benefits ($):

Enter applicable fringe benefits, if any, for each senior/key person.

Funds Requested ($):

The requested salary and fringe benefits for each senior/key person. This field is auto-calculated.

Project Role:

Identify the project role of each senior/key person in this section. Roles should correspond to the roles included on the Section B.240 - R&R Senior/Key Person Profile (Expanded) Form.

Additional Senior/Key Persons:

If funds are requested for more than eight senior/key persons, include all pertinent budget information as identified in this section and attach as a file here. Enter the total funds requested for all additional senior/key persons in line 9 of Section A. This attachment is required if funds are entered in line 9 of Section A. Use the same format as the budget form and include all required information.

Total Funds requested for all persons in the attached file:

Enter the total funds requested for all senior/key persons. This is required information.

Total Senior/Key Persons:

The total funds requested for all senior/key persons.

Special Instructions: 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. 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.

In most circumstances, the salaries of administrative or clerical staff at educational institutions and nonprofit organizations are included as part of indirect costs. Examples, however, of situations where direct charging of administrative or clerical staff salaries may be appropriate may be found at: http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html#exc. The circumstances for requiring direct charging of these services must be clearly described in the budget justification.

For all Postdoctoral Associates and Graduate Students not already named in Section A. Senior/Key Person, individually list names, roles (e.g., PostDoc or Graduate Student), associated months, and salary & fringe benefits requested in the Budget Justification.

The salaries of administrative and clerical personnel should normally be treated as F&A costs. 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 or Secretarial/Clerical Personnel (i.e., administrative and clerical staff) must be appropriately justified in the Budget Justification.

Project Role:

For each project role category identify the number of personnel proposed. List any additional project role(s) in the blank(s) provided, e.g., Engineer, IT Professionals, etc. Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.

Cal. Months:

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

Acad. Months:

Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer). If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification.

Sum. Months:

Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer). If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the 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 each project role. 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 Salary Cap Summary on the NIH grants website or contact your office of sponsored programs.

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: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

Fringe Benefits ($):

Enter applicable fringe benefits, if any, for this project role category.

Funds Requested ($):

This field is auto-calculated.

Total Number of Other Personnel:

This total will auto-calculate. Total Number of Personnel.

Total Other Personnel:

Total Funds requested for all other Personnel.

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

Total Funds requested for all Senior/Key persons and all Other Personnel. This total will auto-calculate.

To navigate to the next page (Sections C through E), click the Next button at the top of the form or use the scroll bar on the left-hand side of the screen.

C. Equipment Description

List of items and dollar amount for each item exceeding $5,000.

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 the budget justification

section. Allowable items ordinarily will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.

Funds Requested:

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

Additional Equipment:

If this section cannot accommodate all the equipment proposed, attach a file in the block provided. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested in the following field.

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

Total funds requested for all equipment listed in the attached file. Dollar amount for each item should exceed $5000.

Total Equipment:

Total Funds requested for all equipment.

D. Travel

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

Identify the total funds requested for domestic travel. Domestic travel includes Canada, Mexico, and U.S. possessions. In the budget justification section, include the purpose, destination, dates of travel (if known), and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).

Foreign Travel Costs:

Identify the total funds requested for foreign travel. Foreign travel includes any travel outside of North America and/or U.S. possessions. In the budget justification section, include the purpose, destination, dates of travel (if known) and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).

Total Travel Cost:

Total Funds requested for all travel.

E. Participant/Trainee Support Costs

Unless specifically stated otherwise in an announcement, NIH and other PHS agencies applicants should leave blank Section E. Note: Tuition remission for graduate students should continue to be included in Section F. Other Direct Costs when applicable.

Additional Instructions for SBIR/STTR:

Not applicable for SBIR/STTR.

Tuition/Fees/Health Insurance:

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

Stipends:

List total funds requested for Participant/Trainee stipends.

Travel:

List total funds requested for Participant/Trainee travel.

Subsistence:

List total funds requested for Participant/Trainee subsistence.

Other:

Describe any other participant trainee funds requested. List total funds requested for any other Participant/Trainee costs described.

Number of Participants/Trainees:

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

Total Participant/Trainee Support Costs:

Total Funds requested for all trainee costs. This field is required if any data has been entered in section E.

F. Other Direct Costs

1. Materials and Supplies:

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

2. Publication Costs:

List the total publication funds requested. 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. In the budget justification include supporting information.

3. Consultant Services:

List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs. In the budget justification also provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant 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. ADP/Computer Services:

List 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 the budget justification, include the established computer service rates at the proposing organization if applicable.

5. Subawards/Consortium/ Contractual Costs:

List 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 the 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 the 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. Please see the Supplemental Instructions, Part III Section 1.1.

6. Equipment or Facility Rental/User Fees:

List total funds requested for equipment or facility Rental/Use fees. In the budget justification, identify each rental user fee and justify.

7. Alterations and Renovations:

List total funds requested for alterations and renovations. In the budget justification, itemize by category and justify the costs of alterations and renovations including repairs, painting, 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. Please refer to the NIH Grants Policy Statement section on "Construction Grants – Public Policy Requirements and Objectives" for more information.

Note, costs for any Alterations and Renovations (A&R) were previously unallowable on applications from foreign institutions, international organizations and domestic applications with foreign subawards. However, an HHS policy change now allows for minor A&R (≤$500,000) on these applications. Not applicable for SBIR/STTR.

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 text to describe any "other" direct costs not requested above. Use the budget justification to further itemize and justify.

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

Total Other Direct Costs:

Total Funds requested for all other direct costs.

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 possible through the efficiencies of scale that under a contract deliver the best value to the government and the intended small businesses

seeking such assistance. 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 lines 8-10.
- Include a detailed description of the services your vendor will provide in the Budget Justification

G. Total Direct Costs (A through F)

Total funds requested for all direct costs.

H. Indirect Costs

Additional Instructions for SBIR/STTR:

Indirect 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. 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 the Department of Health and Human Services [HHS].

If applicable, indicate your organization’s most recent indirect cost rate established with the Division of financial Advisory Services (DFAS), NIH, 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 the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes. If the applicant organization has a current negotiated rate with another Federal agency, the negotiated rate must be adjusted to

treat any independent research and development (IR&D) costs in accordance with HHS policy.

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 2.9 percent (FY 2015) 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.

Below is a list of cost categories NIH considers to be commercialization. In addition, these items include 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.

- **Commercialization cost categories:** market and sales; market research; business development/product development/market plans; legal fees, travel and other costs relating to license agreements and partnerships.

You are encouraged to visit the following Division of Financial Advisory Services (DFAS) Web sites or call the DFAS staff at 301-496-2444 for guidance: Main DFAS website, FAQS. Listing of unallowable and unallocable costs and the related Federal Acquisition Regulation (FAR) citation for each, http://oamp.od.nih.gov/dfas/indirect-cost-branch/indirect-cost-submission/unallowableunallocable-costs.

Indirect Cost Type:

Indicate the type of cost (e.g., Salary & Wages, Modified Total Direct Costs, or Other [explain]). Also indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, "None--will negotiate" and include information for a proposed rate. Use the budget justification if additional space is needed.

Additional Instructions for SBIR/STTR:

SBIR and STTR Phase I Applicants: If your organization does not have a currently effective negotiated F&A 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 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: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-038.html.

Indirect Cost Rate ($):

Indicate the most recent indirect cost rate(s) (also known as Facilities & Administrative Costs [F&A]) 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 that office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency. If this field does not allow a figure greater than 100% to be entered, use two lines to show the entire calculation. This field should be entered using a rate such as “55.5.”

Indirect Cost Base ($):

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

Funds Requested:

Enter funds requested for each indirect cost type. Enter the funds requested for the indirect cost type.

Total Indirect Costs:

Total funds requested for indirect costs.

Cognizant Federal Agency:

Enter the name of the cognizant Federal Agency, name and phone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter “None.”

Special Instructions: Foreign Organizations (Non-domestic [non-U.S. Entities]):

Foreign institutions and international organizations may request funds for limited F&A costs (8 percent of modified total direct costs less equipment) to support the costs of compliance with

HHS and NIH requirements including, but not limited to, 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.

I. Total Direct and Indirect Institutional Costs (G + H)

Total Funds requested for direct and indirect costs.

Additional Instructions for SBIR/STTR:

Ensure that the direct costs and the indirect costs (G+H) on Section F-K EQUAL the Total Direct and Indirect Costs (G+H) on the Cumulative Budget page.

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.

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

Generally, a fee is not allowed on a grant or cooperative agreement. Do not include a fee in your budget, unless the program announcement specifically allows the inclusion of a "fee" (e.g., SBIR/STTR). 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 to small business concerns receiving awards under the SBIR/STTR program. 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 the budget justification. The amount requested for the fee should be based on the following guidelines: (1) it must be consistent with that paid under contracts by the PHS for similar research conducted under similar conditions of risk; (2) it must take into account the complexity and innovativeness of the research to be conducted under the SBIR/STTR project; and (3) 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. Budget Justification

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. Only one file may be attached. The attachment is required.

Use this section to list the names, role (e.g., PostDoc or Graduate Student), associated months, salary and fringe benefits for all Postdoctoral Associates and Graduate Students included in Budget Section B. Other Personnel.

The salaries of administrative and clerical personnel should normally be treated as F&A costs. 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.

For all individuals classified as administrative/secretarial/clerical, provide a justification documenting how they meet all four conditions. NIH ICs may request additional information for these positions in order to assess allowability.

Include a justification for any significant increases or decreases from the initial year budget. Justify budgets with more than a standard escalation from the initial to the future year(s) of support. Also use this section to explain any exclusions applied to the F&A base calculation.

If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. See Section B.310 - R&R Subaward Budget Attachment(s) Form.

Completing Budget Periods 2-5:

If funds are being requested for more than one budget period, you must complete a separate detailed budget for each year of support requested. To navigate to screens for the next budget period, click the **Next Period** button at the top of the 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted and outlined in red) and/or confirm/update any pre-populated information before the **Next Period** button is activated. If no funds are requested for a required field, enter "0." Note the Budget Justification is also a required item and must be attached before the **Next Period** button is activated.

Supplemental/Revision Application:

For a supplemental/revision application, show only those items for which additional funds are requested. 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.

When authorized or requested by the appropriate NIH IC, applicants may submit applications with more than 5 budget periods. In these situations complete the detailed budget for periods 1-5 as usual. However, include the same level of detail for Period 6 in the Budget Justification along with an explanation of the situation. Also, be sure to include a cover letter that addresses these extra budget periods, and include the IC Program Official's preapproval as part of the Cover Letter PDF.

Cumulative Budget

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

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

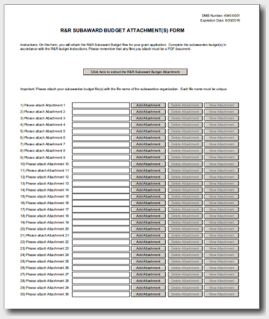
B.310 - R&R Subaward Budget Attachment(s) Form

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

This form is only required when the prime grantee is submitting a detailed budget using the R&R Budget Form.

Do not use this subaward/consortium budget form for applications using the PHS 398 Modular Budget Form.

View larger image



A complete subaward/consortium budget form (including the budget justification section) should be completed by each consortium grantee organization. Separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

For any subaward or consortium sites, it is appropriate and expected that someone may be designated as the consortium lead investigator responsible for ensuring proper conduct of the project or program at that site. However, when completing the Project Role for the consortium lead investigator, the project role of “PD/PI” should only be used if the entire application is being submitted under the Multiple PI policy. Otherwise, this individual should be assigned some other project role in the senior/key personnel section of the application. Also, the role of Co-PD/PI is not currently used by NIH and other PHS agencies. Assigning an individual(s) the role of "Co-PD/PI" will not identify the application as a Multiple PD/PI application. Although NIH now recognizes the role of “Co-Investigator,” if applicants wish to use the role of “Consortium PI” or some other similar role, select “Other” for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field.

Consortium/Contractual F&A Costs:

NIH continues to support the policy established in April 2004, (revised in November 2004) regarding applications that involve consortium/contractual F&A costs (See NOT-OD-05-004). This policy allows applicants to exclude consortium/contractual F&A costs when determining compliance for any application where a direct cost limit applies. The use of the SF424 (R&R) application with separately submitted subaward/consortium budgets allows NIH to take advantage of a system validation for this policy. When an application is submitted in response to a program with a direct cost limit, the eRA system will perform the calculation by taking the total direct costs requested by the prime/parent organization in their detailed budget, and subtracting all subaward/consortium F&A from each and every subaward budget attached. When the validation calculation equals or exceeds the respective direct cost limit, the application will receive a warning. There are circumstances, when the system does not have sufficient information to exclude all allowable F&A costs. Applicants should document in their budget justification, how their budget falls below the direct cost limit (not applicable for SBIR/STTR).

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

This form accommodates a set number of separate subaward budgets (30). If you are submitting an application with more subaward budgets than the form allows, the remaining budgets should be converted

to PDF and included as part of Section K. Budget Justification of the parent budget.

Reminder, the sum of all subaward budgets; e.g., those attached separately and those provided as part of the budget justification, must be included in Line F.5 Subawards/Consortium/Contractual Costs of the project budget.

To start the process, the applicant organization should:

- Select the Subaward Budget Attachment Form from the Optional Documents in the Grant Application Package.
- Open the form, and click the **Click here to extract the R&R Subaward Budget Attachment** button in the middle of the form. A “SAVE” dialog box appears.
- Save the file locally using the first ten letters of the consortium organization’s name and use “.pdf” as the file extension. (The extracted file is an Adobe PDF file.) Once you have saved the file there is no need to extract another budget attachment. Doing so may cause you to lose any data already stored in the saved file.
- E-mail the extracted, saved form to the consortium grantee. Note: consortium grantees must have installed a compatible version of Adobe Reader before they can complete the form. The consortium grantee should complete all the budget information as instructed in Section B.300 - R&R Budget Form. The Budget Type should be set to Subaward/Consortium. Organizational DUNS and Name of Organization fields must reflect that of the subaward/consortium grantee.
- The consortium grantee must complete the budget form and e-mail it back to the applicant organization.
- Return to the Subaward Budget Attachment Form and attach the consortium grantee’s budget to one of the blocks provided on the form.

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

Complete all budget periods in the R&R Budget form for your 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, 2016 – Dec 31, 2016
- period 2 - Jan 1, 2017 – Dec 31, 2017
- period 3 - Jan 1, 2018 – Dec 31, 2018
- period 4 - Jan 1, 2019 – Dec 31, 2019
- period 5 - Jan 1, 2020 – Dec 31, 2020

The budget period numbers and dates should be the same in the R&R Budget forms for the subawards.

The R&R Budget forms do not allow for "empty" budget periods. They include several required fields which must be completed (even for inactive periods) in order to successfully submit.

- Provide the following information for inactive budget periods:
- Organization DUNS
- Budget Type = Subaward/Consortium
- Budget Period Start/End Dates (align with budget periods and dates of the prime budget)

- In section 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

Note this approach may cause a validation warning regarding the NIH $500,000 per year limit on direct costs, therefore you should document in both the cover letter and the subaward budget justification that the subaward is only active for specific periods of the prime. Appropriate NIH staff has access to the cover letter and reviewers have access to the budget justification. This documentation will make the date correlation immediately apparent and will help avoid any confusion.

Additional Instructions for SBIR/STTR:

SBIR

In 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. 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).

If the application is selected for an award, the Authorized Organization Representative (AOR) will need to certify 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 NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

In Phase II, normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. 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).

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 Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form.

STTR

In Phase I and Phase II, at least 40% of the work must be performed by the small business concern 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 Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form.

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. The small business concern will include this letter as an attachment upload in Section B.400 - PHS 398 Research Form, Consortium/Contractual Arrangements.

In addition, a small business concern 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 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.

A small business concern 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. A small business concern 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.**

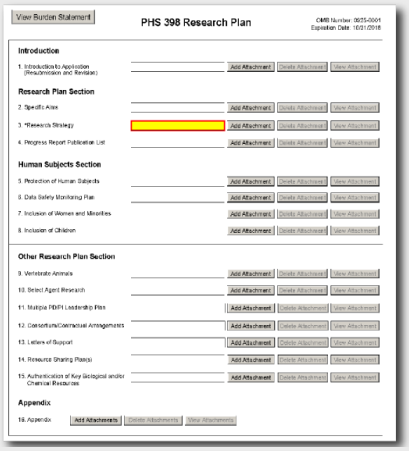
A fee cannot be entered for a subaward/consortium budget. Fee is allowable only for the small business applicant organization budget page.

STTR: If more than one Subaward is included in the STTR application, identify the single, partnering research institution 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

Additional Instructions for SBIR/STTR:

Your SBIR/STTR 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 this program solicitation. It should be self-contained and written with the care and thoroughness accorded to papers for publication. Review the application carefully to ensure that information essential for evaluation is included. The scientific and technical merit of the proposed research is the primary concern for all research supported by NIH, CDC, FDA, and ACF.

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 this solicitation.

A firm must not propose market research, patent applications, or litigation. The research may be carried out through construction and evaluation of a laboratory prototype, where necessary.

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

- **Proprietary Information:** Sections 2.3.11.2 and 2.3.11.2.2 of the NIH Grants Policy Statement

- **Page Limits:** http://grants.nih.gov/grants/forms_page_limits.htm
- **Formatting Attachments:** http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

Introduction

1. Introduction to Application (for Resubmission or Revision only)

NIH policy allows a thirty-seven month window for resubmissions (A1 applications). The NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows. See NIH Notice NOT-OD-12-128 and NOT-OD-14-074 for additional information/clarification of NIH policy.

Required only if Type of Application is Resubmission or Revision. See specific instructions on the content of the introduction at http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-application-submission.htm. First time (new) applications should not include an Introduction unless specified in the FOA.

Follow the page limits for the Introduction in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless otherwise specified in the FOA.

Attach this information as a PDF file.

Research Plan Section

2. Specific Aims

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

The Specific Aims attachment is required unless otherwise specified in the FOA. Follow the page limits for the Specific Aims in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless specified otherwise in the FOA.

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 and Phase IIB 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."

Attach this information as a PDF file.

3. Research Strategy

This attachment is required. Follow the page limits for the Research Plan, unless specified otherwise in the FOA.

Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in Section B.220 - R&R Other Project Information Form, Bibliography and Reference Cited.

Follow the page limits for the Research Strategy in the table of page limits http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.

1. Significance

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

For Phase II, 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 Item 15 (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.
- If your study(s) involves human subjects, the sections on the 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.
- Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 5, below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

Additional Instructions for SBIR/STTR:

Provide a tentative sequence or timetable for the project.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

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

Preliminary Studies for New Applications:

For new applications, include information on Preliminary Studies. 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 help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.

Additional Instructions for SBIR/STTR:

Preliminary Studies for 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 section.

Progress Report for Renewal and Revision Applications.

For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. For any studies meeting the NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children etc.) as part of the progress report, particularly if relevant to studies proposed in the renewal or revision application. You should not submit a PHS Inclusion Enrollment Report form unless the enrollment is part of new or ongoing studies in the renewal or revision application.

Additional Instructions for SBIR/STTR:

Progress Report for Phase II and Phase IIB Competing Renewal and Revision Applications 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).

A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment; do not include that information here.

Attach this information as a PDF file.

4. Progress Report Publication List (Renewal Applications Only)

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. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, or arose from AHRQ funding provided after 2/19/16 (see https://grants.nih.gov/grants/guide/notice-files/NOT-HS-16-008.html), provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Additional Instructions for SBIR/STTR:

Phase II and Phase IIB 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. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material.

Human Subjects Section

5. Protection of Human Subjects

Refer to Supplemental Instructions, Part II Section 4.1.

Complete this section if you answered "yes" to the question "Are human subjects involved?" on the Section B.220 - R&R Other Project Information form. If the answer is "No" to the question but your

proposed research involves human specimens and/or data from subjects you must provide a justification in this section for your claim that no human subjects are involved. Follow the instructions provided in the Application Guide and the FOA regarding the Protection of Human Subject attachment.

Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

Attach this information as a PDF file.

6. Data Safety Monitoring Plan

Refer to Supplemental Instructions, Part II Section 4.1.5

Complete this section if you answered "yes" to Item 1, Clinical Trial of the Section B.210 - PHS 398 Cover Page Supplemental Form.

Attach this information as a PDF file.

7. Inclusion of Women and Minorities

Refer to Supplemental Instructions, Part II. This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the Section B.200 - R&R Other Project Information form and the research does not fall under Exemption 4.

Also, please refer to Section B.500 - PHS Inclusion Enrollment Report of these instructions as well as the Supplemental Instructions, Part II(Section 4.2, 4.3, and 5.6) for more information on submitting PHS Inclusion Enrollment Report form as part of your application.

Attach this information as a PDF file.

8. Inclusion of Children

Refer to Supplemental Instructions, Part II (Section 4.4 and 5.8).

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the Section B.200 - R&R Other Project Information form and the research does not fall under Exemption 4.

Attach this information as a PDF file.

Other Research Plan Section

9. Vertebrate Animals

Complete this section if you answered "yes" to the question "Are Vertebrate Animals Used?" on the Section B.200 - R&R Other Project Information form.

If Vertebrate Animals are involved in the project, address each of the following criteria listed below.

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" section. 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 to minimize discomfort, distress, pain, and injury.

For additional information, see http://grants.nih.gov/grants/olaw/VAChecklist.pdf. Do not use the Vertebrate Animals section to circumvent the page limits of the Research Strategy.

Provide a concise, complete description of the animals and proposed procedures.

- The responses to the criteria below must be well-integrated with the other sections. There should be sufficient detail in the responses for peer reviewers and NIH staff to evaluate. Additional details, if any, may be included in the Research Strategy.
- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites.
- An incomplete application will not be considered for review. It will be considered incomplete if the above criteria are not addressed.
- If plans for the use of animals have not been finalized, explain when and how animals are expected to be used.
- If an award is made, the grantee must provide detailed information on the criteria above, and verification of IACUC approval. These must be submitted to the NIH awarding office prior to the involvement of animals.

An applicable Animal Welfare Assurance will be required if the grantee institution does not have one (see Supplemental Instructions, Part III Section 2.2 for more information).

Attach this information as a PDF file.

10. Select Agent Research

Select agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See http://www.selectagents.gov/.

If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available at http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html.

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.

If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where select agent(s) will be used.
    - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.
    - *An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”
3. Provide a description of all facilities where the select agent(s) will be used.

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

If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.

Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award.

Attach this information as a PDF file.

11. Multiple PD/PI Leadership Plan

For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. 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, process 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. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.

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 Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

Attach this information as a PDF file.

12. Consortium/Contractual Arrangements

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. The signature of the Authorized Organization Representative on the (Section B.200 - SF 424 (R&R), Item 19) 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.

Additional Instructions for SBIR/STTR:

SBIR:

Phase I SBIR Applications: Normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern. 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 SBIR Applications: Normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. 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).

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 attributable to each party, unless otherwise described and justified in Section B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements

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 small business concern 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 costs and fee) attributable to each party, unless otherwise described and justified in Section B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

Certification showing the cooperative R&D arrangement between the small business concern 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 small business concern should convert the letter from the partnering research institution into a PDF attachment, and include it as part of Section B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

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.

Attach this information as a PDF file.

13. Letters of Support (e.g., Consultants)

Attach all appropriate 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 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. 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 year

anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.

Attach this information as a PDF file.

14. Resource Sharing Plan(s)

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

Note: 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.

Attach this information as a PDF file.

15. Authentication of Key Biological and/or Chemical Resources

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. No more than one page is suggested.

- 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.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095 and NOT-OD-16-011).

Attach this information as a PDF file.

Appendix

16. Appendix

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.

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, please refer to NOT-OD-11-080.

Use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements will not be reviewed.

Applications may include the following materials in the appendix (note, however, that some FOAs do not permit publications):

- Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications:
    - Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
    - Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
- Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.
- Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the appendix as necessary

For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions 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.

Items that must **not** be included in the appendix:

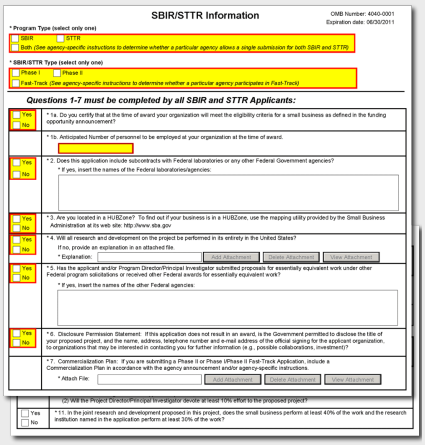
- Unpublished theses or abstracts/manuscripts submitted (but not yet accepted) for publication.
- Digital photographs or color images of gels, micrographs, etc. are no longer accepted as appendix material. These images must be included in the Research Strategy PDF. However, images embedded in publications 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.

B.440 - SBIR/STTR Information Form

In conjunction with the other SF424 (R&R) forms and PHS 398 forms, NIH, CDC, FDA, and ACF SBIR/STTR grant applicants must also complete and submit the "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 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

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

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 relevant letters following letters from consultants and collaborators in Item 13, Letters of Support in the PHS 398 Research Plan Form.

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

If you are applying under the SBIR program, check the SBIR box. If you are applying under the STTR program, check the STTR box. If a particular agency allows a single submission for both STTR & SBIR, check the Both box. A selection is required. Note HHS does not accept 'Both' as a choice.

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

If you are submitting a Phase I application, check the Phase I box. If you are submitting a Phase II application, check the Phase II box. When submitting a Phase II application, please include the Phase I SBIR/STTR grant number in Item #4a (Federal Identifier) on the SF424 (R&R) form. If you are submitting a Fast-Track application, check the Fast-Track box. A selection is required.

1a. Certification of Small Business Eligibility

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 the Yes box. Otherwise, check the No box. A selection is required.

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

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?

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

3. Are you located in a HUBZone?

If you are located in a HUBZone, check the Yes box. 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.

Otherwise, check the No box. A selection is required.

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

If all research and development on the project will be performed in its entirety in the United States, check the Yes box. Otherwise, check the No box and use the Add Attachment button below, to attach an explanation. A selection is required.

If you have answered "no" to question 4 above, please prepare an explanation of the research and development that is being performed outside the United States, in a separate file. Then use the Add Attachment button to the right of this field to attach the file and complete this entry. When you click Add Attachment, browse to where you saved the file, select the appropriate file and then click Open to complete the action.

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 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 the Yes box and insert the names of the other Federal agencies in the space provided. Otherwise, check the No box. A selection is required.

6. Disclosure Permission Statement

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 the Yes box. Otherwise check the No box. A selection is required.

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

7. Commercialization Plan

Applicable to all Phase II and Phase IIB Applications, Phase I/Phase II Fast-Track Applications, and Commercialization Readiness Pilot Program (CRP) Applications.

If you are submitting a Phase II, Phase IIB, Phase I/Phase II Fast-Track or Commercialization Readiness Pilot Program (CRP) application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. To attach a Commercialization Plan file, click the Add Attachment button to the right of this field, browse to where you saved the file, select the file, and then click Open.

All Phase II, Phase IIB, Fast-Track and Commercialization Readiness Pilot Program (CRP) Applications must include a succinct Commercialization Plan.

The Commercialization Plan is limited to 12 pages. Be succinct. There is no requirement for applicants to use the maximum allowable pages allotted to the Commercialization Plan.

Create a document entitled, “Commercialization Plan,” and provide a description in 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 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, and subsequent 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. (It is very important that you understand and know the competition.)

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 consider taking that will constitute at least a temporal barrier to 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, service. Describe how your staffing will change to meet your revenue expectations.

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 relevant letters following letters from consultants and collaborators in Section B.400 -PHS 398 Research Plan Form, Item 13.

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

SBIR-Specific Questions

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

If you have received SBIR Phase II awards from the Federal Government, check the Yes box and use the **Add Attachment** button below to attach a company commercialization history in accordance with agency-specific instructions. Otherwise check the No box.

1. 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 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, and 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?

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

A selection is required for SBIR applications only.

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?

Check the Yes box only if both of the following conditions is 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 the No box if either of these two conditions (or both) is false.

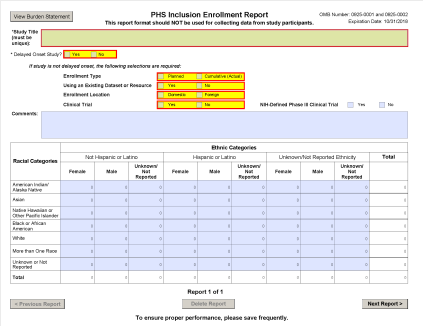
11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

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 the Yes box. Otherwise, check the No box.

B.500 - PHS Inclusion Enrollment Report

The PHS Inclusion Enrollment Report form 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 format should NOT be used for collecting data from study participants. To ensure proper performance of the form, please save frequently.



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: 10/31/2019

*Study Title (must be entered)

* 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.

See below for the forms descriptions and please refer to Supplemental Instructions, Part II Section 4.3 for additional guidance on how and when to use the PHS Inclusion Enrollment Report.

View larger image

Study Title:

Enter a unique title that describes the study that the participants will be involved in. If there is more than one study, provide a separate Study Title for each. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.

Delayed onset study?

Select whether the study is considered delayed onset. This 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. Additional guidance on whether a study meets the criteria to be considered delayed onset can be found in Section 2, Scenario D of the Supplemental Instructions, Part II. If the study is delayed onset, select YES. If the study is not delayed onset, select NO. This is a required field.

If you have answered "No" to delayed onset, you must answer the following and complete the enrollment table:

Enrollment Type:

Select whether the table reflects Planned Enrollment of individuals to be recruited into the study or Cumulative (e.g., actual) Enrollment for 1) participants already recruited into the study or 2) studies using an existing dataset or resource. This is a required field.

Using an existing dataset or resource?

Select whether this study involves use of an existing dataset or resource. This 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 and this FAQ. This is a required field.

Enrollment Location:

Select whether the participants described in the inclusion enrollment report are based at a US or non-US site. At a minimum, participants at US and non-US sites must be reported separately even if for the same study. For additional guidance on working with non-US populations refer to this FAQ. This is a required field.

Clinical Trial:

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

Agency-Defined Phase III Clinical Trial:

Select whether the study is an agency-defined Phase III clinical trial. This is a required field.

Comments:

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. Maximum 500 characters.

Racial Categories:

American Indian/Alaska Native:

Enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

Asian:

Enter the expected number of females and males (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Asian and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

Native Hawaiian or Other Pacific Islander:

Enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

Black or African American:

Enter the expected number of females and males (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; Enter the expected number of females and males (in the respective fields) who are Black or African American and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

White:

Enter the expected number of females and males (in the respective fields) who are White and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields)

who are White and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

More than One Race:

Enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

Unknown or Not Reported:

Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. These are required fields.

Total:

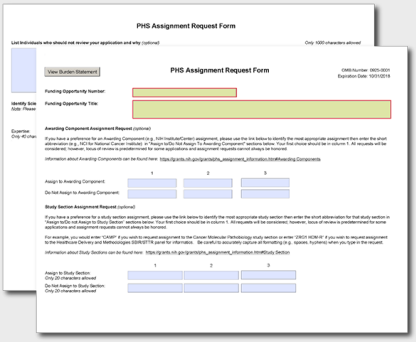
The total fields at the bottom are auto-calculated to total all racial categories for females, males and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino and all racial categories for females, males and individuals of unknown/not reported sex/gender who are Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on “Enrollment Type” Cumulative. The total fields at the right are auto-calculated to total all individuals in a given racial category.

B.600 - PHS Assignment Request Form

The optional 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 application, and it will not be made available to program staff or 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 now, this optional information must be provided on the Assignment Request Form and not in the Cover Letter Attachment.


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 for that Awarding Component 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, focus 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#AwardingComponents

	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, focus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter "CDAMP" 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 ZSRG/ZTR panel for information. 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			

View larger image

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 application to NIH scientific review groups (SRGs) and special emphasis panels (SEPs).

This form is optional and may be omitted from your application submission if you do not wish to make any specific assignment or review requests. There is no requirement that all fields in the form are completed; you have the flexibility to enter a single request or provide extensive information using this form.

Awarding Component Assignment Request (optional)

This section of the form is optional. You may request up to three institutes/centers for assignment of your application

Assign to Awarding Component:

Enter preferences for NIH IC assignment in the boxes in the “Assign to” row. Use the column labeled “1” to enter your first choice.

Do Not Assign to Awarding Component:

You may request that your application not be assigned to a specific NIH IC by entering that information in the boxes in the “Do Not Assign To” row.

In most cases, you will only want to make one or two requests; there is no need to make an entry in all six boxes. The hyperlink in this section of the form (http://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents) will take you to a web site where descriptions of the science covered by all NIH institute/centers can be found, including links to other PHS agency information.

To facilitate accurate communication of your request to NIH referral and review staff, please use the short abbreviation for the requested NIH IC (e.g., NCI for the National Cancer Institute). While NIH staff will seriously consider all assignment requests, in some cases the locus of review is pre-determined and assignment requests cannot be honored.

Study Section Assignment Request (optional)

This section of the form is optional. You may request up to three SRGs or SEPs for assignment of your application.

For this section, you will need to accurately type in the short abbreviation of the SRG / SEP you wish to request. The hyperlink in this section of the form (http://grants.nih.gov/grants/phs_assignment_information.htm#StudySection) will take you to a site where you can find more information about how to identify CSR and NIH SRGs and SEPs, including their short abbreviations. 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.

Assign to Study Section:

Enter the short abbreviations(s) for SRGs / SEPs to which you would like your application assigned in the "Assign to" row. Use one box per individual SRG/ SEP request. Type your first choice in the column labeled "1".

Do Not Assign to Study Section:

If you wish to request that your application not be assigned to a particular SRG/SEP, enter that information in the boxes found in the "Do Not Assign To" row.

In most cases, you will only want to make one or two requests; there is no need to make an entry in all six boxes.

Please note that while the majority of NIH research grant and fellowship applications are reviewed by the Center for Scientific Review (CSR), some are assigned to individual institute/center review groups and some applications 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.

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

Provide sufficient information (e.g., name, organizational affiliation) so that the SRO can correctly identify the individual, and provide sufficient information so that the SRO can confirm a conflict of interest for the review. Simply stating "Dr. John Smith is in conflict with my application" is not helpful. Maximum 1000 characters.

Identify expertise needed to review your application (optional)

Five fields are provided if you wish to identify general or specific types of expertise needed for the review of your application. Maximum 40 characters/field. Do not enter names of individuals you would like to review your application.

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

View Burden Statement

PHS 398 Cover Page Supplement

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*					