FORMS VERSION D SERIES

UPDATED MARCH 25, 2016

GENERAL 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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G.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.

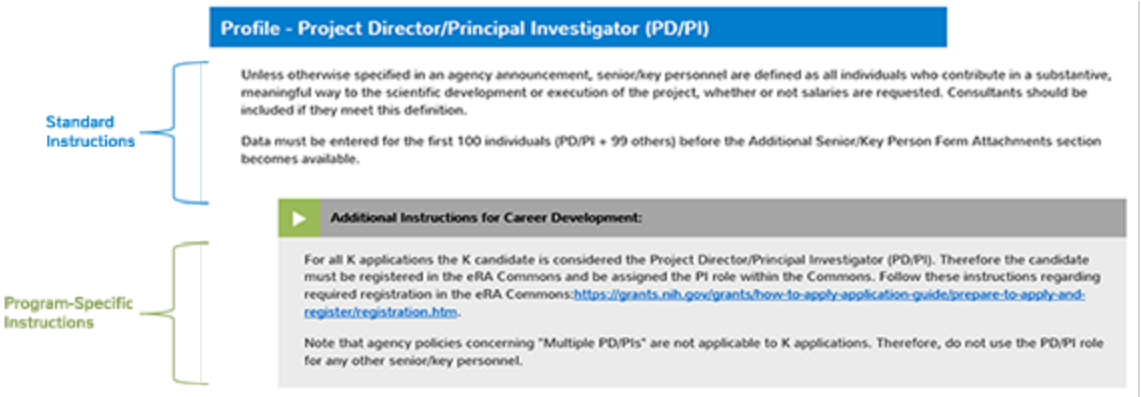
Step 3. Choose which application instruction format you prefer to use.

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.

G.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

G.120 - Significant Changes

Modifications include the following:

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 Career Development Award Supplemental Form

- New “Candidate Information and Goals for Career Development” attachment
  - Combines “Candidate’s Background”, “Career Goals and Objectives”, and “Candidate’s Plan for Career Development/Training Activities during Award Period” attachments into a single attachment
- New “Data Safety Monitoring Plan” attachment
- New “Authentication of Key Biological and/or Chemical Resources” attachment
- Updated Citizenship selections
- Reorganization of attachments
- Field order and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

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 Modular Budget

- Indirect (F&A) Costs section changed to dynamically add indirect costs rather than providing static fields for four entries
- Minor 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 398 Research Training Program Plan

- Removed “Background’ and “Recruitment Plan to Enhance Diversity” attachments (information previously included in these attachments moved to existing “Program Plan” attachment)
- New “Plan for the Instruction in Methods for Enhancing Reproducibility” attachment
- New Data Safety Monitoring Plan attachment
- Format and label changes, including categorizing attachments into sections
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS 398 Training Budget

- Minor label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS 398 Training Subaward Budget Attachment(s) Form

- Streamlined instruction text
- 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 Fellowship Supplemental Form

- New “Applicant’s Background and Goals for Fellowship Training” attachment
    - Combines “Doctoral Dissertation and Other Research Experience”, “Goals for Training and Career”, and “Activities Planned Under Award” attachments into a single attachment
- New “Letters of Support from Collaborators, Contributors, and Consultants” attachment
- New “Description of Institutional Environment and Commitment to Training” attachment
- New “Data Safety Monitoring Plan” attachment
- New “Authentication of Key Biological and/or Chemical Resources” attachment
- New Vertebrate Animals questions added:
    - Are animals euthanized? Yes/No
    - If Yes, is method consistent with AVMA guidelines? Yes/No
    - If No to AVMA guidelines, describe method/provide scientific justification
- Updated list of values for the “Field of Training for Current Proposal” field; changed from 4-digit codes to 3-digit codes
- Updated Citizenship selections
- Reorganization of attachments
- Format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Inclusion Enrollment Report

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

G.130 - Program Overview

Quick Links

- Research and Other ("R" Series)
- Individual Research Career Development Award (CDA) Application ("K" Series)
- Institutional Research Training and Career Development Program Applications ("T" Series)
- Individual Fellowship Applications (“F” Series)
- Multi-Project Applications ("M" Series)
- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)

Research and Other ("R" Series)

The purpose of Research and Other awards is to provide support for health-related research and development based on the mission of the NIH. Some examples of support include pilot studies; conferences and scientific meetings; small research projects; institutional training and Director program projects; resource programs; and new, exploratory and developmental research projects; and may be in the form of grants or cooperative agreements.

Additional research instructions will be denoted by a yellow box and "Additional Instructions for Research" heading.

Before Applying:

- **Become familiar with Activity Code:** Applicants should become familiar with the research activity code for which support is being requested. These include many “R” activity codes, as well as some “DP”, “G”, “S”, and “U” activity codes. A comprehensive list of all activity codes is also available here: https://grants.nih.gov/grants/funding/ac_search_results.htm.
- **Refer to your specific FOA:** It is important to refer to your FOA for specific information associated with the award mechanism including the eligibility requirements, review criteria, award provisions, any special application instructions, and names of individuals who may be contacted prior to submission for additional or clarifying information.
- **Contact Awarding Component:** It is strongly recommended that applicants consult with the NIH Scientific/Research contact of the appropriate awarding component prior to submitting an application as eligibility criteria, support levels, and availability of awards may vary among NIH Institutes or Centers and other PHS agencies.

Individual Research Career Development Award (CDA) Application ("K" Series)

The purpose of Career Development Awards is to provide individual and institutional career development opportunities to candidates at the postdoctoral, early career, and mid-career levels.

Note that these instructions do not cover applications for K12 and other institutional career development programs. Institutions planning such applications should consult the applicable Funding Opportunity Announcement (FOA).

Additional career instructions will be denoted by a green box and “Additional Instructions for Career Development” heading.

Before Applying:

- **Become familiar with Activity Code**: Applicants should become familiar with the K activity code for which support is being requested - https://researchtraining.nih.gov/programs/career-development.
- **Refer to your specific FOA**: It is important to refer to your FOA for specific information associated with the award mechanism including the eligibility requirements, requirements for a mentor or mentors, review criteria, award provisions, any special application instructions, and names of individuals who may be contacted prior to submission for additional or clarifying information.
    - FOAs and other guidelines are available on the NIH K-Kiosk website http://grants.nih.gov/training/careerdevelopmentawards.htm.
    - Announcements for various career award opportunities are issued periodically in the NIH Guide for Grants and Contracts, a weekly electronic publication (http://grants.nih.gov/grants/guide/index.html).
- **Contact Awarding Component:** It is strongly recommended that applicants consult with the NIH Scientific/Research contact of the appropriate awarding component prior to submitting an application as eligibility criteria, support levels, and availability of awards may vary among NIH Institutes or Centers and other PHS agencies.

Note: A few individual K-series programs supported by the NIH include a delayed-award activation and/or two award phases (e.g., K22, K99/R00). NIH intramural researchers may be eligible to apply for these awards. The FOA will include any additional and/or specific instructions that must be followed when applying for such support.

Follow these instructions for submitting the required reference letters for applicable programs, such as career development and individual fellowship awards: http://grants.nih.gov/grants/forms/reference-letter.htm. Referees must submit reference letters through the eRA Commons by the application due date.

The following chart provides a summary of the existing Career Development programs. Since this information is subject to change, prospective applicants are encouraged to review the K-Kiosk for the most current program information.

Summary of Research Career Development Award Programs

Program	Description	Mentor	Reference Letter
K01	Mentored Research Scientist Development Award	Yes	Yes
K02	Independent Scientist Award	No	No
K05	Senior Scientist Award	No	No
K07	Academic Career Award	*	*
K08	Mentored Clinical Scientist Development Award	Yes	Yes
K18	Career Enhancement Award	Yes	Yes
K22	Career Transition Award	*	Yes
K23	K23 Mentored Patient-Oriented Research Career Development Award	Yes	Yes
K24	Mid-Career Investigator Award in Patient-Oriented Research	No	No
K25	Mentored Quantitative Research Career Development Award	Yes	Yes
K26	Mid-Career Investigator Award in Mouse Pathobiology Research	No	No
K99/R00	NIH Pathways to Independence (PI) Award	Yes	Yes

*Varies with career status and source of award. Check the Funding Opportunity Announcement (FOA).

Institutional Research Training and Career Development Program Applications ("T" Series)

The purpose of Research Training Awards is to provide institutional research training opportunities (including international) to trainees at the undergraduate, graduate, and postdoctoral levels.

These instructions apply both to NIH-supported Ruth L. Kirschstein National Research Service Award (NRSA) institutional research training and career development programs (e.g., T32, T34, T35, T36, T90, K12) and to non-NRSA training programs (e.g. T15, T37, D43, D71, U2R).

Note that non-NRSA training and career development programs operate under different regulatory authorities, and, while much of the information may be the same, it is important for individuals interested in those programs to carefully read the applicable Funding Opportunity Announcement (FOA) for specific program information and special application instructions. Non-NRSA training programs may have different eligibility requirements, due dates, award provisions, and review criteria.

Additional training instructions will be denoted by a blue box and “Additional Instructions for Training” heading.

Before Applying:

- **Become familiar with Activity Code:** Applicants should become familiar with the Research Training Activity code and the purpose of the specific program for which support is being requested https://researchtraining.nih.gov/programs/training-grants.
- **Refer to specific FOA:** Applicants should carefully review the applicable FOA which contains more specific information associated with the award mechanism and the names of individuals who may be contacted for additional or clarifying information prior to submission of an application.
  - Announcements for various training programs are issued periodically in the NIH Guide for Grants and Contracts, a weekly publication (http://grants.nih.gov/grants/guide/index.html).

Payback Service Requirement: Please note that for Kirschstein-NRSA programs that include postdoctoral trainees, the Program Director must explain the terms of the payback service requirement to all prospective postdoctoral training candidates. A complete description of the service payback obligation is available in the NIH Grants Policy Statement.

Prospective applicants are encouraged to review the T Kiosk for the most current program information.

Summary of Institutional Training Programs

Activity Code	Program Description	NRSA?
D43	International Research Training Grants	No
D71	International Research Training Planning Grant	No
K12	Institutional Mentored Clinical Scientist Development Program Award	No
T32	National Research Service Award (NRSA) Institutional Research Training Grant	Yes
T34	MARC Undergraduate Student Training in Academic Research (U-STAR) National Research Service Award (NRSA) Institutional Research Training Grant	Yes
T35	National Research Service Award (NRSA) Short-Term Institutional Research Training Grant	Yes
T36	National Research Service Award (NRSA) Short-Term Institutional Research Training Grant	Yes
T90	Training for a New Interdisciplinary Research Workforce	Yes
U2R	International Training Cooperative Agreement	No

Individual Fellowship Applications ("F" Series)

This section contains instructions and other useful information for preparing Kirschstein NRSA and non-NRSA Fellowship Applications to the National Institutes of Health (NIH) and the Agency for

Healthcare Research and Quality (AHRQ).

Kirschstein-NRSA Programs: The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. Certain specialized individual fellowships, such as the predoctoral fellowships (F31 and F30), postdoctoral fellowships (F32), senior fellowships (F33), and other institute-specific fellowship programs are provided under this authority.

Non-NRSA Programs: Fogarty International Center (FIC) and National Library of Medicine (NLM) also have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

Additional fellowship instructions will be denoted by an orange box and "Additional Instructions for Fellowship" heading.

Before Applying:

- **Become familiar with Activity Code:** Applicants should become familiar with the "F" activity code for which support is being requested.
- **Refer to specific FOA:** Before applying for an F award, applicants should carefully review the applicable Funding Opportunity Announcement (FOA) for the fellowship of interest, noting especially the eligibility requirements, requirements for a mentor, review criteria, award provisions, and any special application instructions. Each FOA contains more specific information associated with the award mechanism and includes names of individuals who may be contacted prior to submission of an application for additional or clarifying information.
    - Guidelines for NIH fellowships may be found on the NIH Web Site at https://researchtraining.nih.gov/programs/fellowships.
    - Guidelines for the AHRQ fellowships may be found at http://www.ahrq.gov/funding/training-grants/index.html.
- **Contact Awarding Component:** It is strongly recommended that applicants consult with the appropriate NIH IC or AHRQ staff prior to submitting an application as not all predoctoral, postdoctoral, and senior fellowships are supported by each IC and AHRQ.
    - A list of contacts specifically for extramural training at the NIH ICs can be found at https://researchtraining.nih.gov/tac-roster.
    - For contacts at AHRQ, see http://www.ahrq.gov/funding/training-grants/contacts.html.

Follow these instructions for submitting the required reference letters for applicable programs, such as career development and individual fellowship awards: http://grants.nih.gov/grants/forms/reference-letter.htm. Referees must submit reference letters through the eRA Commons by the application due date.

The following chart provides a list of fellowship activity codes. Since this information is subject to change, prospective applicants are encouraged to review the F-Kiosk for the most current information and links to Funding Opportunity Announcements (FOAs).

Summary of Individual Fellowship Award Programs

Activity Code	Program Description	NRSA?
F05	International Research Fellowships	No
F30	Individual Predoctoral NRSA for M.D./Ph.D. Fellowships	Yes
F31	Predoctoral Individual National Research Service Award	Yes
F32	Postdoctoral Individual National Research Service Award	Yes
F33	National Research Service Awards for Senior Fellows	Yes
F37	Medical Informatics Fellowships	No
F38	Applied Medical Informatics Fellowships	No

Multi-Project Applications ("M" Series)

A Multi-Project Application is a single submission with multiple, interrelated components that share a common focus or objective. A component is a distinct, reviewable part of a multi-project application for which there is a business need to gather detailed information as defined in a particular Funding Opportunity Announcement (FOA). Each component includes the data collection identified for its specific component type. Components typically include general information (component organization, project period, project title, etc.), performance sites, proposed work to be accomplished and a budget.

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

- **A Single Overall Component:** The Overall component describes the entire application and provides an overview of how each of the additional components fit together.
- **One or more Other Component Types:** Other component types (e.g., Admin Core, Project, Core) will vary by opportunity and will be specified in the FOA.
- **Summaries:** Information is automatically compiled from the data provided by the applicant in the individual components and included in the agency assembled application to help reviewers and staff work with the application. These are system-generated summaries and will be presented in the assembled application as part of the Overall Component. Summaries will be generated for the following information when applicable: Component Summary, Performance Sites, Human Subjects, Clinical Trials, Human Embryonic Stem Cells, and Vertebrate Animals, Budgets, and Senior/Key Personnel, including Biosketches.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

Additional multi-project instructions will be denoted by a red box and "Additional Instructions for Multi-Project" heading.

Before Applying:

- **Become familiar with specific FOA:** It is imperative that applicants become familiar with the specific FOA for which support is being requested. Before applying, applicants should carefully review the applicable FOA noting the special application instructions.
    - The FOA will specify the types of Other Components that should be used when preparing the application, whether each component is optional or required and any restrictions on the number of times each component can be included in a responsive application (e.g., 2-3 Projects are required).

Collaborating with Other Organizations

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

Depending on the role of the collaborating organization in the project, there are two approaches to structuring a component.

1. Collaborating Organization as the Lead of a Component:

When the bulk of the leadership and work on a component (other than the Overall) is performed by a collaborating organization, then that organization can be set up as the lead organization for that component. All the component forms (including the SF 424 R&R form and R&R Budget form) are completed using the collaborating organization's information. On the R&R Budget form, use the Budget Type "Project" to identify it as the primary budget for the component and provide the collaborating organization's DUNS number and name.

Any other organizations involved in the component (including the applicant organization) are included in subaward/consortium budget forms.

From an administrative perspective the entire component (minus any work done by the applicant organization) is treated as a subaward/consortium to the applicant organization. The structure of the application reflects where the proposed work is being done, not the flow of funds. eRA systems use the DUNS numbers (not the "Project" vs "Subaward/Consortium" Budget Type designation) included on budget forms to sort out the flow of funds.

2. Collaborating Organization as a Consortium in a Component:

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

For components or subawards that are not active for all periods of the entire application, fill out the minimal required information for the inactive budget periods and complete all information for the active budget periods.

For example, Project-004 does not start until budget period 2. In the Project-004 R&R Budget form for period 1 include the following information:

- Select the appropriate Budget Type ("Project" for the main component budget or "Subaward/Consortium" for subaward/consortiums within that component)
- Provide the Budget Period 1 Start and End Dates
- In Section A - Senior/Key Person, include the project lead specifying their role, .01 effort under Calendar months, $0 for Requested Salary and $0 for Fringe Benefits
- Attach your Budget Justification, including an explanation for the delayed start

Complete the remaining budget periods following standard instructions.

Multi-Project Application Component Forms

You must complete a set of forms for each component.

The assembled application image created for a Multi-Project application has a predetermined order. The Overall Component is always first and includes the system-generated data summaries. Other component types follow in alphabetical order (e.g., Cores before Projects). Components of the same type are grouped together in the order designated in ASSIST (or the order submitted to Grants.gov if not using ASSIST) and given sequential numbers (e.g., Core-001, Core-002, Project-001, Project-002). For information on multi-project application assembly, see http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

Component Data Forms

Form	Overall	Admin Core, Core Project, Other named components	Indiv Career Dev	Career Dev	NRSA Training
SF424 R&R cover	✓	✓	✓	✓	✓
PHS 398 Cover Page Supplement	✓	✓	✓	✓	✓
R&R Other Project Information	✓	✓	✓	✓	✓
Project/Performance Sites	✓	✓	✓	✓	✓
R&R Sr/Key Person Profile (Expanded)	✓	✓	✓	✓	✓
PHS Inclusion Enrollment Report		Optional	Optional	Optional	
PHS Assignment Request Form	Optional				
R&R Budget		✓	✓	✓	
R&R Subaward Budget Attachment		Optional	Optional	Optional	
PHS 398 Training Budget					✓
Training Subaward Budget					Optional

Form	Overall	Admin Core, Core Project, Other named components	Indiv Career Dev	Career Dev	NRSA Training
Attachment Form					
PHS Additional Indirect Costs	Optional				
PHS 398 Research Plan	✓	✓			
PHS 398 Career Development Award Supplemental Form			✓		
PHS 398 Research Training Program Plan				✓	✓

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 Com-ponent	Commercialization Plan?	Grant Type
Phase I	Establish the tech-	$150,000	NIH, CDC,	No	New/Resub

Application Name	Definition	Budget / Time Guidelines*	Participating HHS Component	Commercialization Plan?	Grant Type
	nical merit and feasibility of the proposed R&D efforts	total costs, 6 - 12 months	FDA, ACF		
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

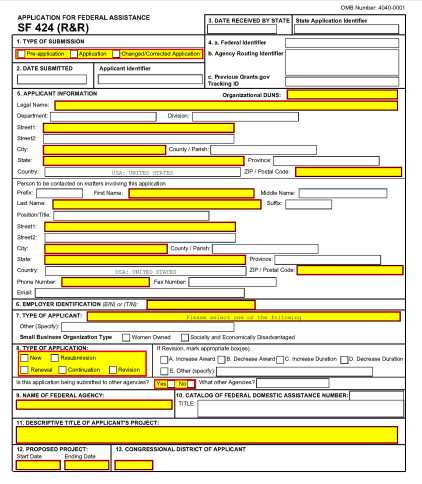
* At NIH, deviations from the budget guidelines are acceptable, but must be well justified and discussed with HHS program staff prior to submission. According to statutory guidelines, total funding support (direct costs, indirect costs, and fee) normally may not exceed $150,000 for Phase I awards and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

G.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

Additional Instructions for Multi-Project:

All the SF424 (R&R) form fields are collected for the Overall Component.

Only a subset of data fields from the SF424 (R&R) form are collected for the Other Components. These are:

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

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 Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

3. Date Received by State and State Application Identifier

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

Additional Instructions for Multi-Project:

Not required for Other Components.

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 Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

4.c. Previous Grants.gov Tracking ID

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

Additional Instructions for Multi-Project:

Not required for Other Components.

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 Multi-Project:

Required for Other Components.

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 Multi-Project:

Not required for Other Components.

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 Fellowship:

This information is for the Applicant Organization, not a specific individual AOR or Fellowship PD/PI.

Additional Instructions for Multi-Project:

Optional for Other Components.

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).

Additional Instructions for Career Development:

Unless stated in the applicable FOA, individual K awards are usually not renewable nor are they supplemented/revised (contact awarding component staff if clarification is needed). Therefore, the applicant should generally check "new" or "resubmission." "Renewal" applications are accepted only for a few K programs; thus this value should only be checked if a specific FOA states Renewals are accepted.

Additional Instructions for Fellowship:

Unless stated in the applicable FOA, individual F awards are usually not renewable nor are they supplemented/revised (contact the awarding institute or center staff if clarification is needed). Therefore, the applicant should generally check "new" or "resubmission." "Renewal" applications are accepted only for a few F programs; thus this value should only be checked if a specific FOA states that Renewals are accepted.

Additional Instructions for Multi-Project:

Not required for Other Components.

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 Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

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 Multi-Project:

Required for the Other Components.

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 Career Development:

The requested period of support must be within specified limits for the type of K award requested.

Additional Instructions for Training:

The usual starting date for an institutional training grant is July 1, but there are other possible starting dates. Refer to the Key Dates listed in the FOA and the webpage of Standard Due Dates for Competing Applications (http://grants.nih.gov/grants/funding/submissionschedule.htm). Many PHS awarding components restrict due dates and review dates to once a year. Applicants are strongly encouraged to contact the appropriate awarding component staff before submitting an application.

Additional Instructions for Fellowship:

The requested period of support must be within specified limits for the type of F award requested.

Additional Instructions for Multi-Project:

Required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

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 G.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 Career Development:

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

must be affiliated with the applicant organization. For additional information on creating affiliations for users in the eRA Commons, see: https://era.nih.gov/commons/commons-help/175.htm.

Note: For some career transition award programs (e.g., K22) the applicant may apply WITHOUT an institutional affiliation. These individuals should refer to the specific funding opportunity announcement (FOA) for application instructions.

Multiple PD/PIs do not apply to career development applications.

Additional Instructions for Fellowship:

Provide the name of the individual Fellowship applicant (considered the PD/PI for F award programs). If the Fellowship applicant is not located at the applicant organization at the time the application is submitted, the information should reflect where the Fellowship applicant can be reached prior to the requested award start date. If the PD/PI is not located at the applicant organization at the time of submission, the Commons account for the PD/PI must be affiliated with the applicant organization. For additional information on creating affiliations for users in the eRA Commons, see: https://era.nih.gov/commons/commons-help/175.htm.

Multiple PD/PIs do not apply to fellowship applications.

Additional Instructions for Multi-Project:

Not required for Other Components.

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 Fellowship:

Applicants should refer to the NIH/OER Research Web site (https://researchtraining.nih.gov) for current stipend and other budgetary levels, and enter the total amount being requested for the entire period of support. This amount includes the applicable stipend amount, the actual tuition and fees, and the standard institutional allowance.

If new stipend or other payment levels for Kirschstein-NRSA fellowships are announced after the time of application, these amounts will be automatically adjusted at the time of award.

Extraordinary Costs. Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.

Additional Instructions for Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Fellowship:

Not applicable to fellowships. Enter $0.00.

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."

Additional Instructions for Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

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.

Additional Instructions for Multi-Project:

Not required for Other Components.

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**.

Additional Instructions for Fellowship:

Not applicable for fellowships. Leave blank.

Additional Instructions for Multi-Project:

Not required for Other Components.

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 G.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.)

Additional Instructions for Career Development:

Mentored CDA must include a cover letter that contains a list of Referees (including name, departmental affiliation, and institution). The cover letter is only for internal use and will not be shared with peer reviewers. Applicants for independent CDAs are encouraged to include a cover letter with the application.

Additional Instructions for Fellowship:

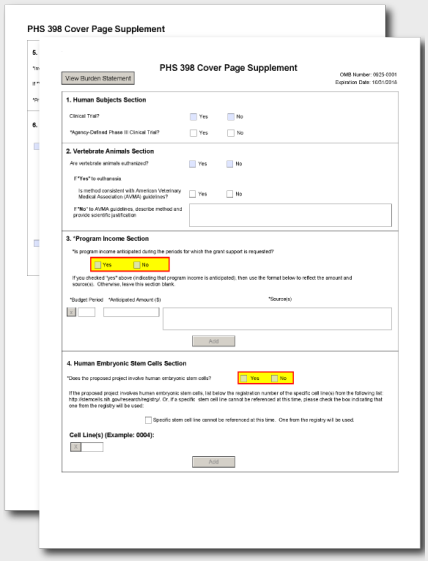
Individual fellowship applicants must include a cover letter that contains a list of Referees (including name, departmental affiliation, and institution). The cover letter is only for internal use and will not be shared with peer reviewers.

Additional Instructions for Multi-Project:

Not required for Other Components.

G.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.

Additional Instructions for Multi-Project:

Answer required if component includes Human Subjects.

If Yes on any Other Component, then the answer must be Yes on the Overall Component.

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.

Additional Instructions for Training:

If you checked “Yes” to Human Subjects and “Yes” to Clinical Trial on the R&R Other Project Information form, you must check either “Yes” or “No” to indicate whether plans include or potentially include trainee participation in projects that are NIH-Defined Phase III Clinical Trials.

Additional Instructions for Multi-Project:

Answer required if component includes a Clinical Trial. If Yes on any Other Component, then the answer must be Yes on the Overall Component.

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.

Additional Instructions for Multi-Project:

Answer required if component includes Vertebrate Animals. If Yes on any Other Component, then the answer must be Yes on the Overall Component.

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.

Additional Instructions for Training:

Check “No”.

Additional Instructions for Multi-Project:

If Yes on any Other Component, then the answer must be Yes on the Overall Component. The budget period, anticipated amount, and source information provided in the Overall should summarize the information provided in Other Components.

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.

Additional Instructions for Training:

Check “Yes” if training plans include or potentially will include involvement of trainees in projects that include human embryonic stem cells.

Additional Instructions for Multi-Project:

Answer required if component includes Human Subjects. If Yes on any Other Component, then the answer must be Yes on the Overall Component.

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).

Additional Instructions for Training:

If "Yes", list the 4-digit NIH Registration Number of the specific cell line(s) from the NIH Human Embryonic Cell Registry, or check the box indicating that the specific stem cell line cannot be referenced at this time. Applications proposing the use of hESC must either specify a cell line(s) from the NIH Stem Cell Registry that will be used in the proposed research or, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at the time of application and a certification that one from the Registry will be used. The justification should be included in the Research Strategy section of the application. For additional guidance, see NIH Guide Notice NOT-OD-12-111 Notice of Impending Change in Peer Review Criteria and Submission Requirements for NIH Applications Involving Human Embryonic Stem Cells.

Note that individual project HESC information is not required at the time of application, but will be requested as Just-in-time (JIT) information prior to award. At that time, the NIH will require information regarding project title, mentor and specific cell line(s) from the registry (http://grants.nih.gov/stem_cells/registry/current.htm) for each trainee utilizing human embryonic stem cells in a research project. Trainees may not participate in human embryonic stem cell related research until this information is provided.

Additional Instructions for Multi-Project:

List all cell lines that pertain to the specific component. All cell lines from Other Components must be entered in the Overall Component cell line table.

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.

Additional Instructions for Training:

Not applicable - leave blank.

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.

Additional Instructions for Career Development:

Not applicable; a change in PD/PI is not allowed for K awards.

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:

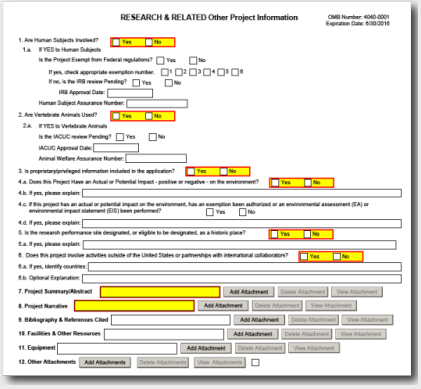
If this application reflects a change in grantee institution, insert the name of the former institution here.

Additional Instructions for SBIR/STTR:

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

G.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

Additional Instructions for Fellowship:

Note: This form should be completed in consultation with the Sponsor and Administrative Officials at the Sponsoring Institution

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.

Additional Instructions for Training:

Check "Yes" if training plans include or potentially will include involvement of trainees in projects that include human subjects as defined by 45 CFR 46. Check "Yes" even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If no activities involving human subjects are planned, check the No box, and skip the rest of this block. This field is required.

In many instances, trainees supported by institutional training grants will be participating in research that is supported by separate research project grants for which the IRB approval or a determination of exemption exists. Existing IRB approval may be sufficient for trainees, provided that the IRB determines the research would not be substantially modified by the participation of a trainee.

Trainees may only participate in non-exempt human subjects research that is being conducted by an institution that has an approved FWA on file with OHRP and which has IRB approval. The awardee institution is responsible for maintaining documentation of FWA and IRB approvals for all trainee research projects and providing these to NIH if requested.

In instances where trainees will design and conduct independent human subjects research as part of the training award, human subjects may not be involved and trainees may not participate in research involving human subjects unless the engaged institution has an approved FWA on file with OHRP, and IRB approval has been obtained. Certification of the date of IRB approval must be submitted to NIH, and NIH requirements for human subjects protections must be addressed (see instructions in the Supplemental Instructions, Part III Section 1.5.2, and the NIH Grants Policy Statement.

The institution must ensure that trainees who will be involved in the design or conduct of research involving human subjects receive training in human subjects protections. It is the institution's responsibility to ensure that trainees are properly supervised when working with human subjects.

These policies apply to all Performance Sites.

Additional Instructions for Multi-Project:

If activities involving human subjects are planned at any time during the proposed project at any performance site and/or on any Other Component, check Yes for the Overall Component and complete the remaining questions as instructed using the unique guidance below for selected data items.

For Other Components, answer only the "Are Human Subjects Involved?" and "Is the Project Exempt from Federal regulations?" questions.

1.a. If YES to Human Subjects

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.

Additional Instructions for Multi-Project:

If the Overall Component exemption is E4 then no other exemption number can be set for any Other Component.

For Other Components, must answer if Human Subjects is Yes.

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.

Additional Instructions for Multi-Project:

Complete only for the Overall Component when applicable. Not Collected for Other Components.

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.

Additional Instructions for Fellowship:

In many instances, the Fellow will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption has been designated. This review or exemption designation is sufficient, provided that the IRB determines that participation of the Fellow does not substantially modify the research.

If the sponsoring institution has an approved FWA on file with OHRP that covers the specific activity, provide the number and the latest date of approval by the IRB of the proposed activities. This date must be no earlier than one year before the due date for which the application is submitted.

Additional Instructions for Multi-Project:

Complete only for the Overall Component when applicable. Not Collected for Other Components.

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.

Additional Instructions for Fellowship:

If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and add the PHS Fellowship Supplemental Form, 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 PHS Fellowship Supplemental Form, Vertebrate Animals, attachment in the Other Research Training Plan, and verifying an IACUC approval to the awarding component. See the PHS Fellowship Supplemental Form (Section G.430 - PHS Fellowship Supplemental Form) for a specific data item on “Indefinite Vertebrate Animal Use.”

Additional Instructions for Training:

Check “Yes” if training plans include or potentially will include trainees in projects involving the use of live vertebrate animals at any time during the proposed project period. Otherwise, check “No”, and skip the rest of this block. This field is required.

In many instances, trainees supported by institutional training grants will be participating in research that is supported by a separate research project grants for which the IACUC review and approval exists. This existing IACUC approval may be sufficient for trainees, provided that the research would not be substantially modified by the participation of a trainee.

Note that trainees may only participate in vertebrate animal research that is being conducted at an institution that has an approved Animal Welfare Assurance on file with OLAW and that has IACUC approval. The awardee institution is responsible for maintaining documentation of the Animal Welfare Assurance and IACUC approvals for all trainee research projects and providing these to NIH if requested.

In instances where trainees will design and conduct independent vertebrate animal research as part of the training award, vertebrate animals may **not** be involved and trainees may **not** participate in research involving vertebrate animals unless the institution has an approved Animal Welfare Assurance on file with OLAW and IACUC approval has been obtained. Verification of IACUC approval (within 3 years) must be submitted to NIH, and NIH requirements for research involving vertebrate animals must be addressed. Prior to conducting any animal activities, the grantee must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the instructions in Section G.420 - PHS 398 Research Training Program Plan, Vertebrate Animals.

The institution must ensure that trainees are enrolled in the institution's animal welfare training and occupational health and safety programs for personnel who have contact with animals. It is the institution's responsibility to ensure that trainees are properly supervised when working with live vertebrate animals.

These policies apply to all Performance Sites.

Additional Instructions for Multi-Project:

If activities involving vertebrate animals are planned at any time at the Overall Component or at any Other Component, at any performance site, check yes on the Overall component and complete the remaining questions as instructed using the unique guidance below for selected data items. If no, skip the rest of block 2. For Other components, answer only the "Are Vertebrate Animals Used?" question.

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.

Additional Instructions for Multi-Project:

Complete only for the Overall Component when applicable. Not Collected for Other Components.

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.

Additional Instructions for Multi-Project:

Complete only for the Overall Component when applicable. Not Collected for Other Components.

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.

Additional Instructions for Fellowship:

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.

In many instances, the Fellow will be participating in research supported by research project grants for which the IACUC review has been obtained. This review is sufficient, provided that participation of the Fellow does not substantially modify the research. The appropriate grant(s) must be identified along with the IACUC approval date(s).

The Sponsoring Institution must ensure that the Fellow is enrolled in the institution's animal welfare training and safety programs for personnel who have contact with animals, as appropriate. It is also the Sponsoring Institution's responsibility to ensure that the Fellow is properly supervised when working with live vertebrate animals.

Also see the instructions for the PHS Fellowship Supplemental Form for additional information (Section G.430 - PHS Fellowship Supplemental Form).

Additional Instructions for Multi-Project:

Complete only for the Overall Component when applicable. Not Collected for Other Components.

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.

Additional Instructions for Multi-Project:

If Yes on any Other Component, then the answer must be Yes for the Overall Component.

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.

Additional Instructions for Fellowship:

If you have checked "Yes" to 6, applicants to the NIH and AHRQ must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than in a

domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training experience as compared to the training available domestically.

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.)

Additional Instructions for Career Development:

Provide an abstract of the entire application (candidate, environment, and research). Include the candidate's immediate and long-term career goals, key elements of the research career development plan, and a description of the research project.

Additional Instructions for Training:

Summarize the objectives, rationale and design of the research training program. Provide information regarding the research areas and scientific disciplines encompassed by the program. Include a brief description of the level(s) (i.e., undergraduate, predoctoral, postdoctoral, faculty) and duration of the proposed training, the projected number of participating trainees and their anticipated levels of experience. This section must be no longer than 30 lines of text and must follow the required font and margin specifications.

Additional Instructions for Multi-Project:

Required for Overall and Other Components.

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 G.400 - PHS 398 Research Plan Form, Research Plan for separate file uploads and instructions.

Additional Instructions for Training:

Using no more than two or three sentences, describe the relevance of this research training program to public health. In this section, use plain language that can be understood by a general, non-scientific audience.

Additional Instructions for Multi-Project:

Required for Overall Component. Optional for Other Components. See specific FOA to see if this is required for any Other Components. Note Form may show '*' indicating it is a required field, but it is only required for the Overall component and the '*' can be ignored for other components.

9. Bibliography & References Cited

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 G.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

Additional Instructions for Training:

This item should be used only to cite references supporting the need, rationale, and approach for the training program described in the PHS 398 Research Training Program Plan. Do not include lists of publications of project directors, mentors or trainees in this section, as this information will be included in the biosketches and Data Tables.

Additional Instructions for Multi-Project:

Unless specific instructions are provided in the FOA, applicants have the option of including this attachment in the Overall Component, Other Components or both. User-defined bookmarks provided in the Bibliography & References Sited attachment will be included with the bookmarks of the assembled application image in eRA Commons.

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 Career Development:

Provide in the Attachment a detailed description of the institutional facilities and resources available to the candidate. The information provided is of major importance in establishing the feasibility of the goals of the career development plan.

Additional Instructions for Training:

Describe the facilities and resources that will be used in the proposed training program, including any foreign performance sites. Indicate in what ways the applicant organization will support the program, financial or otherwise (e.g., supplementation of stipends, protected time for mentoring, support for student activities). This could also include, for example, space, shared laboratory facilities and equipment, funds for curriculum development, release time for the PD/PI and participating faculty, support for additional trainees in the program, or any other creative ways to improve the environment for the establishment and growth of the research training program.

Additional Instructions for Fellowship:

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

Additional Instructions for Multi-Project:

Unless specific instructions are provided in the FOA, applicants have the option of including this attachment in the Overall Component, Other Components or both.

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.

Additional Instructions for Multi-Project:

Unless specific instructions are provided in the FOA, applicants have the option of including this attachment in the Overall Component, Other Components or both. User-defined bookmarks provided in the Equipment attachment will be included with the bookmarks of the assembled application image in eRA Commons.

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 Fellowship:

Certification Letter for Predoctoral Fellowships (F31) to Promote Diversity

Applications submitted for Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research are required to attach a Certification Letter (titled Diversity_Eligibility_Ltr) from the institution certifying eligibility of the Fellowship applicant for the program. The letter should avoid revealing sensitive personal information, such as the candidate's specific racial/ethnic background or type of disability. The Certification Letter must be on institutional letterhead and scanned so that an institutional official signature is visible.

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:

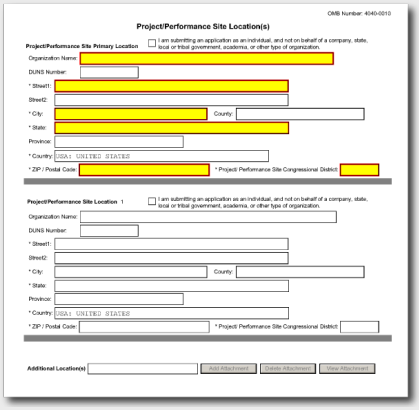
SBIR Application Certification for small business concerns majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms. Applicant small business concerns that are majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms (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.

G.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 G.220 - R&R Other Project Information form, and describe any consortium/contractual arrangements in Section G.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 Career Development:

Indicate where the work described in the Research and Career Development Plans will be conducted including any foreign sites (when applicable).

Additional Instructions for Training:

List all of the locations where training, program management, and the research training experiences described in the Research Training Program Plan will be performed, including any foreign sites. If investigators and trainees at a Project/Performance Site will be engaged in research involving human subjects, it is the responsibility of the applicant organization to assure that all investigators and trainees at the Project/Performance Sites comply with the human subject protection regulations in 45 CFR part 46 and NIH policies for the protection of human subjects. For research involving live vertebrate animals, the applicant organization must supply information for all training sites where animals will be used by trainees. The applicant organization is responsible for assuring that all Project/Performance Sites have a current Animal Welfare Assurance and comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Additional Instructions for Fellowship:

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.

One of the sites indicated must be the sponsoring organization; generally, the Primary Location should be that of the sponsoring organization. Indicate where the training described in the Research Training Plan will be conducted. If there is more than one training site, including any Department of Veterans Affairs (VA) facilities or foreign sites, list them all in the fields provided for Location 1, and additional locations, as necessary.

If there are unusual circumstances involved in the research training proposed, such as fieldwork or a degree sought from an institution other than the one in which the research training will take place, describe these circumstances in Section G.220 - R&R Other Project Information Form, Facilities and Resources.

Foreign Sponsorship: An individual may request support for training abroad. In such cases, the applicant is required to provide detailed justification for the foreign training,

including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training will be considered for funding only when the scientific advantages are clear. The foreign justification should be provided as a separate attachment in Section G.220 - R&R Other Project Information Form, Item 12
.

Additional Instructions for Multi-Project:

Include only the Primary Site in the Overall Component. A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission. ASSIST: Summary Performance Site information is available when using “Preview Application.”

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 G.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

Additional Instructions for Multi-Project:

List all performance sites that apply to the specific component.

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

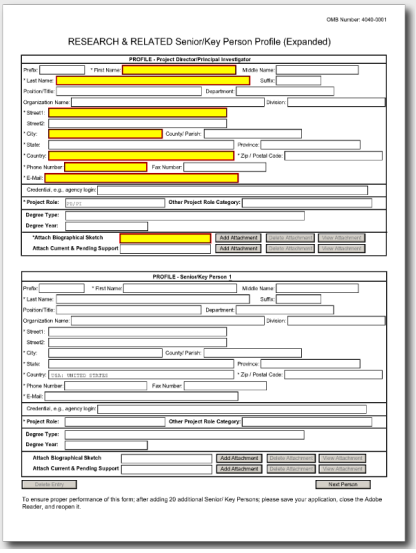
For additional performance site locations, click Next Site to display the fields for Project/Performance Site Locations 2 through 300.

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.

G.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 G.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 G.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 G.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 Career Development:

For all K applications the K candidate is considered the Project Director/Principal Investigator (PD/PI). Therefore the candidate must be registered in the eRA Commons and be assigned the PI role within the Commons. Follow these instructions regarding required registration in the eRA Commons:https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/registration.htm.

Note that agency policies concerning "Multiple PD/PIs" are not applicable to K applications. Therefore, do not use the PD/PI role for any other senior/key personnel.

Additional Instructions for Training:

If multiple PD/PIs are proposed, explain in the Program Plan your rationale for how this will facilitate program administration. If your application involves Multiple PD/PIs, be sure to designate the Contact PI and to assign the PD/PI role to other senior/key persons. Additionally, the application must include a Multi-PD/PI Leadership Plan emphasizing how it will benefit the program and the trainees. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application. See Section G.420 - PHS Training Program Plan for information associated with Multiple Program Directors.

Additional Instructions for Fellowship:

Starting with the PD/PI (Fellowship applicant), provide a profile for each senior/key person proposed.

Note that agency policies concerning "Multiple PD/PIs" are not applicable to F applications. Therefore, do not use the PD/PI role for any other senior/key personnel.

Additional Instructions for Multi-Project:

A summary of Senior/Key Persons followed by their Biographical Sketches will appear in the Overall section of the assembled application image in eRA Commons and will be generated upon submission.

Only list the Contact PD/PI and any Multi-PD/PIs; all with role PD/PI on the Overall Component. Do not list any other Senior/Key personnel for the Overall Component. The PD/PI role should not be used for any personnel in Other Components.

Must provide the eRA Commons username for all PD/PIs. For Other Components, provide the eRA Commons username for person identified in the Profile - Project Director/Principal Investigator section of the form (typically Project Lead).

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.

Additional Instructions for Career Development:

For non-mentored CDAs: Candidates for non-mentored CDAs should not submit Other Support Pages at the time of application unless specified to do so in the applicable FOA.

Updated information on all active support for the candidate, mentor(s), co-mentor(s), and senior/key personnel may be requested by the awarding component prior to award.

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.

Additional Instructions for Multi-Project:

Each Senior/Key individual, including the PD/PI, is allowed one biosketch for the entire application. If an individual will participate on multiple components, chose any single entry to attach the biosketch, make sure it reflects participation on each relevant component.

The PD/PI(s) may include the biosketch in the Overall Component or any Other Component.

Biosketches will not be repeated within each component in the application image.

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.

Additional Instructions for Career Development:

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

Consultants should also be assigned the "Other Professional" role even if they are not committing any specified measurable effort. Then, enter the specific project role under "Other Project Role Category."

Any individuals identified as senior/key personnel who are committing specified measurable effort should be appropriately assigned under Project Role (and Other Project Role Category, if necessary).

Additional Instructions for Training:

The Program Director(s) (in case of multiple PD/PIs), training faculty and any other individuals whose contributions are critical to the development, management and execution of the Research Training Program Plan in a substantive, measurable way (whether or not salaries are reimbursed) should be identified as senior/key persons. These would include co-Director(s), if applicable, and program staff. Since these efforts are not project related research endeavors, they should not be identified in Other Support information. Do not include proposed mentors and training faculty members (other than senior/key persons) in this section. Biographical Sketches for mentors and participating faculty will be included in the PHS 398 Research Training Program Plan Form, Participating Faculty Biosketches.

Additional Instructions for Fellowship:

Fellowship awards require a primary sponsor, and there may be co-sponsor(s), consultants and contributors. All individuals who have committed to contribute to the scientific development and execution of the project, including sponsor and co-sponsors, should be identified as senior/key personnel, even if they are not committing any specified measurable effort to the proposed project. Sponsors and co- sponsors should be assigned the Project Role of “Other Professional” and then enter “Sponsor” or “Co-Sponsor” in the Other Project Role Category field.

Consultants should also be assigned the “Other Professional” role even if they are not committing any specified measurable effort. Then, enter the specific project role under “Other Project Role Category.”

Any individuals identified as senior/key personnel who are committing specified measurable effort should be appropriately assigned under Project Role (and Other Project Role Category, if necessary).

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.

Additional Instructions for Research:

Candidates for diversity and reentry supplement support must provide a Commons Username.

Additional Instructions for Career Development:

Mentors must provide a Commons username (See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-082.html).

Additional Instructions for Fellowship:

Fellowship Sponsors must provide a Commons username (See NOT-OD-14-129).

Additional Instructions for Multi-Project:

Provide the eRA Commons username for person identified in the Profile - Project Director/Principal Investigator section of the form (typically Project Lead).

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.

Additional Instructions for Career Development:

Mentors and co-mentors should be assigned the Project Role of “Other Professional” and then enter “Mentor” or “Co-mentor” in the Other Project Role Category field.

Additional Instructions for Fellowship:

Sponsors, Co-sponsors and doctoral dissertation advisors should use the “Other” category and indicate the appropriate role (e.g. Sponsor) as the role in the “Other Project Role Category.”

Additional Instructions for Multi-Project:

Unless otherwise specified in the FOA, use Project Role of “Other” with Category of “Project Lead” in the Project Director/Principal Investigator section of the form.

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.

Additional Instructions for Multi-Project:

Each Senior/Key individual, including the PD/PI, is allowed one biosketch for the entire application. If an individual will participate on multiple components, chose any single entry to attach the biosketch, make sure it reflects participation on each relevant component.

The PD/PI(s) may include the biosketch in the Overall Component or any Other Component.

Biosketches will not be repeated within each component in the application image.

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 Instructions for Career Development:

For Mentored Career Development Awards, as part of the application submission modified Current and Pending Support pages must be submitted for the mentor and co-mentor(s), but not for the candidate, on the R&R Senior/Key Person Profile (Expanded) page. Provide information on the following selected items for the mentor's and co-mentor's current and pending research support relevant to the candidate's research plan. Each attachment is limited to 4 pages.

Special Instructions for Selected Items of Current & Pending Support for Mentor/Co-Mentors

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Do not include information on overlap and level of effort.

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.

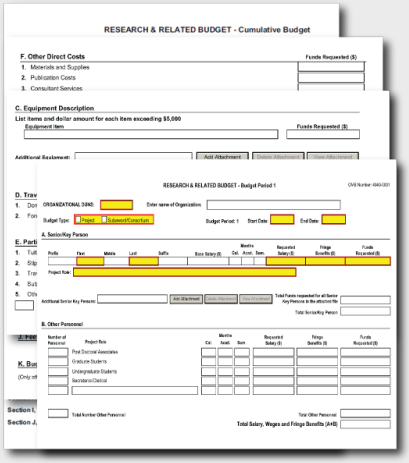
Additional Current and Pending Support(s):

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.

G.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

Additional Instructions for Career Development:

K award mechanisms are not modular; therefore, only the R&R budget form is applicable and only a few budget categories are actually used. Information regarding allowable costs for the candidate and any allowable research development or other costs is included in each K program FOA. Candidates are advised to contact the targeted awarding component if uncertain about allowable amounts for the applicable K award mechanism, keeping in mind that amounts vary with awarding components. The application forms package associated with CDA funding opportunities includes the R&R Budget Form.

Note: NIH intramural candidates applying for transitional career award support (e.g., K22, K99/R00) should follow instructions in the applicable FOA. For the mentored phase of these awards, budgets are negotiated with the sponsoring intramural

laboratory. For awardees who receive approval to transition to the extramural phase, a budget will be required as part of the extramural sponsored application.

Additional Instructions for Training:

This form is required for use in conjunction with the PHS 398 Training Budget for the R90 portion of T90/R90 applications, and is the only budget form that should be used for K12, D43, D71, and U2R applications. Otherwise this form should only be used when allowed or required in an FOA or IC-specific notice or announcement. Follow instructions in Section G.420 - PHS Training Program Plan and in the FOA.

Additional Instructions for Multi-Project:

The only budget information requested in the Overall component is the Section G.200 - SF 424 (R&R) Form, Estimated Project Funding section and Section G.350 - PHS Additional Indirect Costs Form (if applicable). The PHS Additional Indirect Costs form is used to gather any additional information allowable under the grantee's negotiated F&A rate agreement needed to correctly calculate the Facilities and Administrative rate for the overall component's first $25,000 on each subaward that leads an entire component. The PHS Additional Indirect Costs form should not be used when all components are led by the applicant organization.

Budget summaries will appear in the Overall section of the assembled application image in eRA Commons, will be compiled from detailed budget data collected in the Other Components, and will be generated upon submission.

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 G.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.

Additional Instructions for Career Development:

In general this section should include the name of the candidate only. Do not include the mentor(s) or any other senior/key persons. For the candidate, provide the base salary, person months, and requested salary and fringe benefits. For person months, be reminded that K programs include a minimum effort requirement, usually 75% or 9 person months. For the salary column, most NIH ICs limit the amount of salary contribution provided for K programs. However, applicants should include information on actual institutional base salary and fringe benefits, and the actual amount of salary and fringe being requested. ICs may request updated salary information prior to award. Any adjustments based on policy limitations will be made at the time of the award.

The total salary requested must be based on a full-time staff appointment. The salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. The total salary contribution provided by the NIH may not exceed the legislatively mandated salary cap. See: http://grants.nih.gov/grants/policy/salcap_summary.htm.

The sponsoring institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale. However, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case may PHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the career award.

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 G.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

Additional Instructions for Career Development:

In general, leave this section blank.

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.

Additional Instructions for Career Development:

Leave these sections blank.

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

Additional Instructions for Career Development:

Leave these sections blank.

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 Career Development:

Leave these sections blank.

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.

Additional Instructions for Career Development:

Other Direct Costs: In the Material and Supplies field (F.1), enter the total research development support being requested for the initial year of the K award. Usually, a specific total amount is allowed for research development and other costs (tuition, fees, research supplies, equipment, computer time, travel, etc.) that do not require individual cost category identification. Unless instructed differently in the applicable FOA, applicants should enter only the total requested research development support amount in this box. All remaining budget fields in this section should be left blank.

Please note that while this method of entering only the total requested research development support (RDS) costs in section F will be simplest for most applicants, some applicants, including some system-to-system applicants, may instead choose to enter those costs in the applicable detailed budget categories. Please note that when choosing this option it is still the applicant's responsibility to make certain the total RDS costs do not exceed the allowable total. If there are no costs within the research development support costs that affect the Indirect Cost Base calculation, the total RDS should be entered in total in F.1.

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 Research:

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

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

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

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

Additional Instructions for Multi-Project:

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

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

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

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

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 Career Development:

For all K applications, indirect costs (also known as Facilities & Administrative Cost [F&A]) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees and expenditures for equipment) rather than on the basis of a negotiated rate agreement.

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 Career Development:

Indicate the Indirect Cost type as Modified Total Direct Costs.

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."

Additional Instructions for Career Development:

Indicate the indirect cost rate as 8%.

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."

Additional Instructions for Career Development:

Enter "Not Applicable." Alternatively, applicants may provide the name of the cognizant Federal agency, name, and phone number of the individual responsible for negotiating your rate. Either response is acceptable since indirect costs will be reimbursed as 8% of modified total direct costs rather than on the basis of a negotiated rate agreement.

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

Additional Instructions for Career Development:

Use this to provide a detailed description and justification for specific items within the Research Development Support costs; e.g., all equipment, supplies, and other personnel that will be used to help achieve the career development and research objectives of this award.

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.

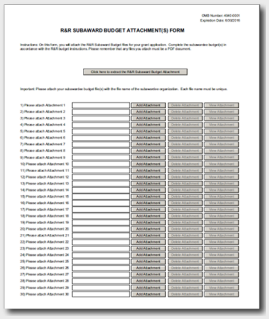
If any of the amounts displayed on this form appears to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such adjustments, you will need to revisit the appropriate budget period form(s), to enter corrected values.

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



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 G.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 G.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.

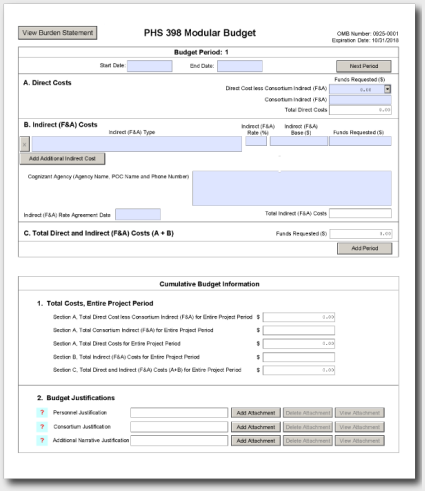
STTR: If more than one Subaward is included in the STTR application, identify the single, partnering research institution on the RI Subaward budget justification page.

G.320 - PHS 398 Modular Budget Form

The PHS 398 Modular Budget Form is only applicable to research applications from domestic organizations that are requesting $250,000 or less per year in direct costs. International organizations and others that do not fall under this definition should use the detailed budget forms described in Section G.300 - R&R Budget Form.

It is important that all applicants refer to their FOA for guidance on which budget form(s) are allowed for your application.

Note that 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. Direct Costs
B. Indirect (F&A) Costs
C. Total Direct and Indirect (F&A) Costs (A+B) Funds Requested ($)
- Cumulative Budget Information

Modular Budget Guidelines

Modular budgets are applicable to certain research grant applications from domestic organizations requesting $250,000 or less per year for direct costs. International organizations and others that do not fall under this definition should use the detailed budget forms described in Section G.300 - R&R Budget Form. Note, consortium/contractual F&A costs are not factored into the direct cost limit. They may be requested in addition to the $250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application.

For all modular budgets, request total direct costs (**in modules of $25,000**), reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year. Provide an additional narrative budget justification for any variation in the number of modules requested.

NIH may request (prior to award) additional budget justification in exceptional circumstances. For further information, see http://grants.nih.gov/grants/funding/modular/modular.htm.

Note that AHRQ does not accept modular budgets.

Using the Modular Budget Form

The Modular Budget Form provides budget fields for up to 5 years of support (e.g., budget periods 1 - 5). If requesting less than 5 years of support, complete only those years requested and leave the others blank.

NOTE: The form allows for up to five budget periods followed by a cumulative budget for all budget periods. The fields are the same for all budget periods. The following instructions can be used for each

Budget Period 1

Start Date:

Enter the requested/proposed start date of the budget period. Use the following format: MM/DD/YYYY.

End Date:

Enter the requested/proposed end date of the budget period. Use the following format: MM/DD/YYYY.

A. Direct Costs

Direct Cost less Consortium Indirect (F&A):

Enter the amount of Direct Costs, less actual consortium indirect (F&A) costs for this budget period. This figure must be in $25,000 increments, and it may not exceed $250,000. Any consortium indirect (F&A) costs are excluded from this figure. This field is required.

Consortium Indirect (F&A):

If this project involves a consortium, enter the actual consortium indirect (F&A) costs for this budget period. If this project does not involve a consortium, leave blank.

Total Direct Costs:

This field auto-calculates.

B. Indirect (F&A) Costs

Indirect (F&A) Type:

Indicate the type of base (for example, Salary & Wages, Modified Total Direct Costs, Other [explain]), and 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 (F&A) 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.

Indirect (F&A) Rate (%):

Indicate the most recent Indirect (F&A) 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.

Indirect (F&A) Base ($):

Enter the amount of the base for each indirect (F&A) type.

Funds Requested ($):

Enter funds requested for each indirect cost type.

Once you have entered all required information for indirect (F&A) costs, press the Add Additional Indirect Cost button to enter information for an additional indirect cost. A total of four indirect (F&A) costs can be added.

Cognizant Agency (Agency Name, POC Name and Phone Number):

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."

Indirect (F&A) Rate Agreement Date:

If you have a negotiated rate agreement, enter the agreement date.

Total Indirect (F&A) Costs:

This field auto-calculates.

C. Total Direct and Indirect (F&A) Costs (A+B) Funds Requested ($)

The total funds requested for direct and indirect (F&A) costs. This field is required.

Once you have entered all required information for budget period 1, press the Next Period button to enter information for the subsequent budget period.

Cumulative Budget Information

1. Total Costs, Entire Project Period

All values for the Cumulative Budget Information are calculated automatically. They equal the summations of the amounts that you have entered previously 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.

2. Modular Budget Justifications

Personnel Justification:

List all personnel, including names, percent of effort and roles on the project. 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.

No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation when estimating the number of modules. For guidance on current salary limitations contact your office of sponsored programs.

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 secretarial/clerical, in addition to the name, percent effort and role, provide a justification documenting how they meet all four conditions. NIH ICs may request additional information for these positions in order to assess allowability.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. This limit should also be used when estimating the number of modules. See: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

Save the information in a single file and click the add attachment button to complete this entry

Consortium Justification:

Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest $1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort, using the metric of person months, and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the total consortium/contractual costs must be included in the overall requested modular direct cost amount.

Attach this information as a PDF file.

Additional Narrative Justification:

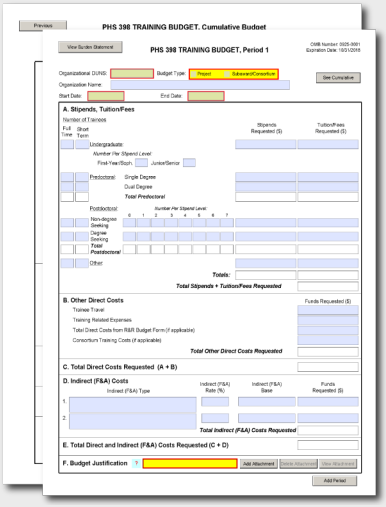
If the requested budget requires any additional justification; e.g, variations in the number of modules requested, save the information in a single file and click the add attachment button to complete this entry.

G.330 - PHS 398 Training Budget Form

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

For current stipend levels and allowable costs, refer to the relevant FOA or consult the PHS awarding component.

Note that the PHS 398 Training Budget form is not applicable for K12, T37, D43, D71, and U2R. Applicants to these grant programs should follow the instructions for the R&R Budget Form (Section G.300 R&R Budget Form) and the FOA (if applicable).



View larger image

Quick Links

- Part A. Stipends, Tuition/Fees
- Part B. Other Direct Costs
- Part C. Total Direct Costs Requested
- Part D. Indirect (F&A) Costs
- Part E. Total Direct and Indirect (F&A) Costs Requested (C+D)
- Part F. Budget Justification
- Cumulative Budget

If you are requesting a budget of $500,000 direct costs or more for any year, contact the awarding component to determine whether you must obtain prior approval before submitting the application. Some Institutes/Centers do not require prior approval. (See Supplemental Instructions, Part III Section 1.4.)

Complete the following for each budget period:

Part A. Stipends, Tuition/Fees

Enter the number of trainees, total stipend amount and total tuition/fees for each trainee category as appropriate.

Stipends:

Use the current Institutional Kirschstein-NRSA stipend schedule, (http://grants.nih.gov/training/nrsa.htm). If a category contains different stipend levels, e.g., for varying levels of postdoctoral experience and/or varying appointment periods, itemize in the appropriate blocks. Enter the total stipends for all categories.

Tuition/Fees:

See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-073.html for NIH policy regarding payment of tuition and fees.

Tuition at the postdoctoral level is limited to that required for specified courses that are to be described in the Budget Justification (Part F.).

Tuition and fees may be requested only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally supported students and postdoctoral fellows. Where applicable, trainees should be divided into non-degree-seeking and degree-seeking categories.

Note that health insurance is not included as part of this budget category. See the Training Related Expenses category below. Grantees should request full needs. The formula currently in effect will be applied by the NIH awarding component at the time an award is calculated.

Part B. Other Direct Costs

Enter the total costs for Trainee Travel, Training Related Expenses, Total Direct Costs from R&R Budget Form (if applicable) and Consortium Training Costs (if applicable).

Trainee Travel

Some NIH awarding components pay a flat rate per trainee for trainee travel for all long-term trainees. See the appropriate FOA and/or contact the awarding component to determine the amount provided for travel. In the budget justification, state the purpose of any travel, giving the number of trips involved, the destinations, and the number of trainees for whom funds are requested. PHS policy requires coach class air travel be used. Justify foreign travel in detail, describing its importance to the training experience. Enter the total amount requested in the Trainee Travel column.

Training Related Expenses (TRE)

Funds to defray other costs of training, such as health insurance (self-only or family), staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the amounts specified in the FOA and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-073.html for each predoctoral and postdoctoral trainee. Based on the number of trainees at the predetermined rate, enter the total dollar figure.

Health insurance (self-only or family, as applicable) is an allowable cost that may be requested as part of training related expenses, but only to the extent that the same health insurance fees are charged to regular non-Federally-supported students and postdoctoral fellows. The allowable TRE amount will be awarded as a lump sum. No further itemization or explanation is required.

The awarding Institute/Center will apply the Training Related Expenses level established for NRSA Institutional programs for the relevant fiscal year at the time of award.

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

Certain FOAs allow funds to cover costs for items other than those specified above. Use Research & Related Budget Pages, Sections A through I and K, to submit those costs. Total Direct Costs from the Research & Related Budget page should be inserted here. This line should not include any applicant indirect costs.

Additional Instructions for Multi-Project:

Not applicable

Consortium Training Costs (if applicable)

If training is occurring at more than one institution, and any transfer of funds between institutions occurs, Section G.340 - PHS 398 Training Subaward Budget Attachment(s) Form should be used. Total the direct costs from the Subaward Budget Attachment Forms and insert here. The applicant institution is responsible and accountable for any arrangements, expenditures, and submission of all required forms when more than one institution is involved in the research training program.

Part C. Total Direct Costs Requested

Total dollar amount of other direct costs requested (automatically calculated).

Part D. Indirect (F&A) Costs

Facilities and Administrative (F&A) costs under Institutional Kirschstein-NRSAs, other than those issued to U.S., state, or local government agencies, will be awarded at 8%, excluding tuition/fees, equipment, and sub-grants and contracts in excess of $25,000.

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

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

Indirect (F&A) Type:

Enter “F&A”

Indirect (F&A) Rate (%):

Enter “8”

Indirect (F&A) Base ($):

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

Funds Requested ($):

Enter the product of Indirect Cost Rate multiplied by Indirect Cost Base.

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

The sum of Total Direct Costs Requested and Total Indirect Costs Requested will be calculated automatically.

Part F. Budget Justification

A detailed justification is to be attached only for the first budget period, but should reflect the entire budget period. Explain in detail the composition of any of the above items, as necessary.

- Itemize tuition and individual fees. If tuition varies, (e.g., in-state, out-of-state, student status) identify these separately.
- If tuition is requested for postdoctoral trainees, the specific courses must be described in the application.
- If trainee travel is not paid at a flat rate per trainee by the awarding component, state the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that PHS policy requires coach class air travel be used.
- Justify the number of training slots (predoctoral and/or postdoctoral) requested. For postdoctoral training slots, justify the stipend levels requested.
- Any foreign travel must be justified in detail, describing its importance to the training experience and considering the type of opportunities available for training, how those opportunities differ from and complement those offered by the grantee institution, and the relationship of the proposed off-site training experience to the career stage of the grantee.

This budget justification should apply only to funds requested on the PHS 398 Training Budget form. When the Research & Related Budget Form is also used, two separate budget justifications are required, each covering the costs required in the particular budget form. Combining the information into a single upload is acceptable; however, each budget form requires a budget justification attachment so the same budget justification will need to be included in both budget forms.

PHS 398 Training Budget, Cumulative Budget

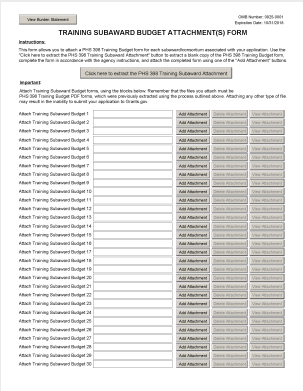
All values on this form are calculated automatically. They present the summations of the amounts that you have entered previously, for each of the individual budget periods. Therefore, no data entry is allowed or required.

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.

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

This form should be used with the PHS 398 Training Budget Form when proposing subawards to other institutions. For applications that require the use of the SF 424 R&R Budget, see instructions in Section G.300 R&R Budget Form.

View larger image



Complete the Subaward Budget for each contractor or collaborating institution. For most programs, this is not common but is usually encountered when a portion of the training program takes place at a site other than the grantee institution via a collaborative or consortium arrangement. In such situations, the grantee institution is responsible and accountable for acceptable training arrangements, expenditure of funds and the submission of all required forms.

Using the Training Subaward Budget Attachment(s) Form:

This form accommodates up to 30 separate subaward budgets. If you are submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of Section G.330 - PHS 398 Training Budget, Budget Justification, of the parent budget (PHS 398 Training 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 Section G.330 - PHS 398 Training Budget, Part B. Consortium Training Costs.

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 "**Select to Extract a Training 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 Adobe Reader before they can complete the form. The consortium grantee should complete all the budget information as instructed in Section G.300 - R&R Budget Form. Note: 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:

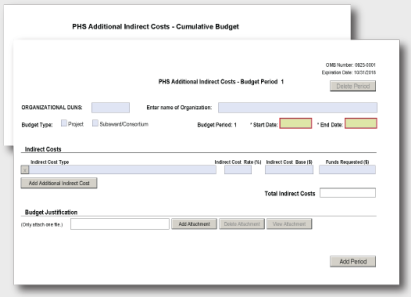
- Organization DUNS
- Budget Type = Subaward/Consortium
- Budget Period Start/End Dates (align with budget periods and dates of the prime budget)
- In section A: Senior/Key Person, provide a single entry including the following:
- PD/PI or subaward lead First and Last names
- Project Role (may default 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.

G.350 - PHS Additional Indirect Costs Form

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

View larger image



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.

Enter name of Organization

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

Budget Type

Project, The budget requested for the primary applicant organization. This field is required.

Start Date

Pre-populated from the R&R SF424. 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.)

Indirect 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.

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.

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."

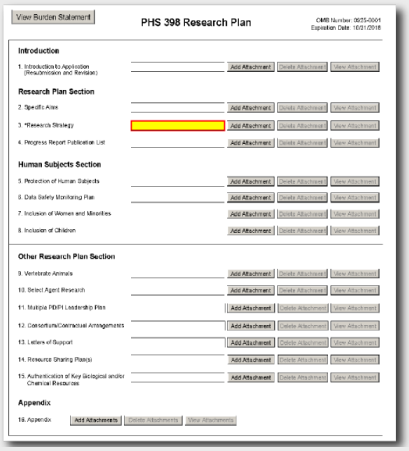
Budget Justification

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.

G.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.



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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.

Additional Instructions for Multi-Project:

Required for Resubmission and Revision applications. Allowed for each Other Component unless otherwise stated in the FOA.

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 Multi-Project:

Required for the Overall Component. Required for Other Components (through eRA validations; not a Grants.gov form requirement).

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.

Additional Instructions for Multi-Project:

Required for Overall and Other Components.

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 G.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 Research:

Describe of the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

Additional Instructions for Multi-Project:

Describe of the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

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 Multi-Project:

Systematically optional for both Overall and Other components.

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 G.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.

Additional Instructions for Multi-Project:

Required for the Other Component. Optional for the Overall Component unless specifically requested in the FOA.

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 G.210 - PHS 398 Cover Page Supplemental Form.

Additional Instructions for Multi-Project:

Required for the Other Component. Optional for the Overall Component unless specifically requested in the FOA.

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 G.200 - R&R Other Project Information form and the research does not fall under Exemption 4.

Also, please refer to Section G.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.

Additional Instructions for Multi-Project:

Required for the Other Component. Optional for the Overall Component unless specifically requested in the FOA.

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 G.200 - R&R Other Project Information form and the research does not fall under Exemption 4.

Additional Instructions for Multi-Project:

Required for the Other Component. Optional for the Overall Component unless specifically requested in the FOA.

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 G.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/VASchecklist.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).

Additional Instructions for Multi-Project:

Complete only for the Other Component when applicable. Not collected for the Overall Component.

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.

Additional Instructions for Multi-Project:

Required if more than one PD/PI is specified on R&R Senior/Key Person Profile form of the Overall Component. Not applicable for Other Components.

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 G.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 Multi-Project:

Optional for both Overall and Other Components

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 G.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 G.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 G.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.

Additional Instructions for Multi-Project:

Optional for both Overall and Other Components.

Additional Instructions for SBIR/STTR:

Phase I, Phase II, Phase IIB, and Fast-Track SBIR/STTR Applications: Involvement of consultants and collaborators in the planning and research stages of the project is permitted. Include with the application letters from each individual and/or collaborator confirming their role(s) in the project. Following is guidance for such documentation: The letter(s) should be prepared on the consultant or collaborator's

letterhead and addressed to the Small Business Concern (SBC). One page is recommended.

At a minimum, each consultant and collaborator letter should (1) verify their commitment to the project; (2) refer to the specific project by name, acknowledging the PD/PI as the lead on the project; and (3) specify what services /tasks the consultant or collaborator will contribute (e.g. expertise, number of hours/ percent of effort, summary of tasks to be completed). For consultants, the letter should also include the rate/charge for consulting services. Also include biographical sketches for each consultant.

For STTR projects, 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.

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

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).

Additional Instructions for Multi-Project:

Required for the Other Components. Optional for the Overall Component unless specifically requested in the FOA.

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 Multi-Project:

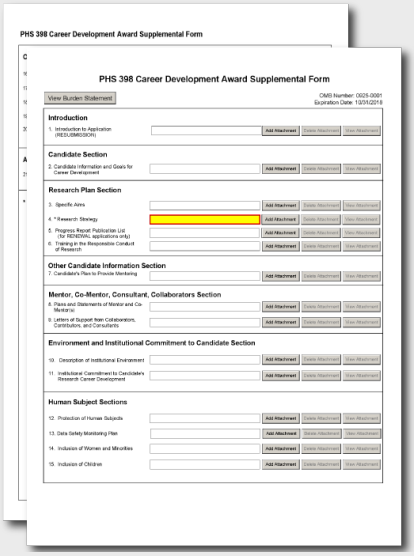
Optional for both Overall and Other Components.

Additional Instructions for SBIR/STTR:

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

G.410 - PHS 398 Career Development Award Supplemental Form

The PHS 398 Career Development Award Supplemental Form is used only for Career Development applications and Multi-Project applications with a Career Development component. This form includes fields to upload several attachments including the specific aims, research strategy, and candidate background and goals section.



View larger image

Quick Links

- Introduction
- Candidate Section
- Research Plan Section
- Other Candidate Information Section
- Mentor, Co-Mentor, Consultant, Collaborators Section
- Environment and Institutional Commitment to the Candidate Section
- Human Subjects Section
- Other Research Plan Sections
- Appendix
- Citizenship

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

The PHS 398 Career Development Award Supplemental Form 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. Some sections are required for all K award applications and some sections are only to be used when required by the FOA. **Be sure to read all instructions in the FOA before completing this section since errors could lead to incomplete or rejected applications**.

Introduction

1. Introduction to Application (for RESUBMISSION 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. 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.

The Introduction is a required attachment for Resubmissions and Revisions. 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.

Candidate Section

2. Candidate Information

This attachment is required. Follow the page limits for Career Developments in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Candidate's Background:

Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. Any additional information not described in the Biographical Sketch Format Page, such as research and/or clinical training experience, may be included in this section.

Career Goals and Objectives:

Describe your short-term and long-term career goals and objectives are, and how the career development award is envisioned to enable you to develop and/or expand your research career. It is important to justify the need for the award. You are encouraged to include a timeline, including plans to apply for subsequent grant support.

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

Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance

your research career. For mentored awards, describe any structured activities that are part of the developmental plan, such as coursework, or workshops that will help you learn new techniques or develop needed professional skills. If coursework is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, other than research, in which you expect to participate. Include a percentage of time involvement for each activity by year, expressed in person months, and explain how the activity is related to the proposed research and the career development plan. For more information about calculating person months, see: http://grants.nih.gov/grants/policy/person_months_faqs.htm

Attach this information as a PDF file.

Research Plan Section

A Research Plan is required for all types of individual K awards. The Research Plan is a major part of the research career development plan. It is important to relate the research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan and launch and conduct an independent research career, or enhance an established research career. For mentored K awards, explain the relationship between the candidate's research on the CDA and the mentor's ongoing research program.

For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be managed; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The Research Plan of a CDA is expected to be appropriate for, and tailored to the experience level of the candidate, and allow him/her to develop the necessary skills needed for further career advancement, and reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the sole part(s) of a CDA research plan. Although candidates for mentored K awards are expected to write the Research Plan, the mentor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful. Although it is understood that CDA applications do not require the extensive detail usually incorporated into regular research applications, a fundamentally sound Research Plan and a reasonably detailed Approach section should be provided.

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

3. Specific Aims

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

State precisely 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.

Attach this information as a PDF file.

4. Research Strategy

This attachment is required. Follow the page limits for the Career Development Award Research Strategy, unless specified otherwise in the FOA.

Organize the Research Strategy in the specified order and using the instructions provided below. 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 G.220 - R&R Other Project Information Form, Bibliography and References Cited.

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

2. Innovation

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

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.
    - For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
- 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 18 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.

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.

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

Attach this information as a PDF file.

5. Progress Report Publication List (for 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, that 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.

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).

Attach this information as a PDF file. Attachments will display in the application image in alphabetical order based on the file name.

6. Training in the Responsible Conduct of Research:

This attachment is required. Follow the page limits for the Career Development Award for Training in the Responsible Conduct of Research in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

For mentored career development awards, describe a plan to acquire instruction in the responsible conduct of research. For independent career awards, describe a plan to obtain or provide instruction in the responsible conduct of research. See Supplemental Instructions Supplemental Instructions, Part III Section 1.16 for information on the NIH Policy on Training in the Responsible Conduct of Research (RCR).

Attach a description of plans for obtaining instruction in the responsible conduct of research. This section should document prior instruction or participation in RCR training during the applicant's current career stage (including the date instruction was last completed) and propose plans to either receive instruction or participate as a course lecturer, etc., in order to meet the once every four-year requirement. The plan should address how applicants plan to incorporate the five instructional parts outlined in the NIH Policy on Instruction in the Responsible Conduct of Research:

1. Format - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable);
2. Subject Matter - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics;
3. Faculty Participation - the role of the mentor(s) and other faculty involvement in the instruction;
4. Duration of Instruction - the number of contact hours of instruction, taking into consideration the duration of the program; and
5. Frequency of Instruction -instruction must occur during each career stage and at least once every four years. See also NOT-OD-10-019.

The plan may include career stage-appropriate individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific

research activities and the societal impact of that research. The role of the mentor in RCR instruction must be described.

Where applicable, Renewal applications must describe the RCR instruction activities undertaken during the project period as well as future plans.

Attach this information as a PDF file.

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring

Include only when required by the specific FOA, e.g., K24 and K05).

Follow the page limits for the Career Development Award Candidates Plan to Provide Mentoring in the table of page limits http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

The plan should provide information about the candidate's commitment to serve as a mentor to other investigators, and describe previous mentoring activities. The plan should describe the setting and provide information about the available pool of mentees with appropriate backgrounds and interests in the same field of science. It should also include information on the candidate's past and proposed mentees sufficient to evaluate the quality of prior mentoring experiences, including the professional levels of mentees, and the frequency and kinds of mentoring interactions between the candidate and the mentees. Describe the productivity of the mentoring relationship for the scientific development of the new scientists as judged by their publications and current research activities. Senior level (K05) candidates should describe any financial and material support from their own funded research and research resources that will be available to their mentees. The candidate's proposed percent effort commitment to the mentoring plan should also be stated, expressed in person months. For more information about calculating person months, see: http://grants.nih.gov/grants/policy/person_months_faqs.htm.

Attach this information as a PDF file.

Mentor, Co-Mentor, Consultant, Collaborators Section

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

Follow the page limits for the Career Development Award Plans and Statements of Mentor and Co-mentors in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

For mentored awards (see Summary of Career Development Award Mechanisms table), the mentor and co-mentor(s) (if applicable) must explain how they will contribute to the development of the candidate's research career. This statement should include all of the following:

1. The plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project and define what aspects of the proposed research project the candidate will be allowed to take with him/her to start their own research program.
2. The source of anticipated support for the candidate's research project for each year of the award period.
3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
4. The candidate's anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.
5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.

All mentored career development applications should identify any and all co-mentors involved with the proposed research and career development program. Co-mentors must specifically address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this CDA. Statements from the mentor(s) and co-mentor(s) documenting their role and willingness to participate in the project. Do not place these statements in the Appendix.

The plans and statements must be appended together and uploaded as a single PDF file.

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

Attach all appropriate letters of support. Follow the page limits for the Career Development Award Letters of Support from Collaborators, Contributors, and Consultants in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. 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. For consultants, letters should include rates/charges for consulting services.

Mentored career development award applications should identify any and all collaborators, contributors, and consultants involved with the proposed research and career development program not already included in Item 7. Letters should briefly describe their anticipated contributions and document their role and willingness to participate in the project.

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

The letters must be appended together and uploaded as a single PDF file.

Environment And Institutional Commitment To The Candidate Section

10. Description of Institutional Environment:

This attachment is required. Follow the page limits for the Career Development Award Description of Institutional Environment in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (See Section G.220 - R&R Other Project Information Form, Facilities and Other Resources), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

Attach this information as a PDF file.

11. Institutional Commitment to Candidate's Research Career Development:

This attachment is required and is limited to one page. Follow the page limits for the Career Development Award Institutional Commitment to Candidate's Research Career Development in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Introduction:

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the CDA. The document should include the institution's agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development and advancement of the candidate during the period of the award.

Because of the diverse types of K awards, applicants should consult the FOA to determine the level of commitment required for a particular application.

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

1. Agree to release the candidate from other duties and activities to devote the required percentage of time for development of a research career, as specified by the FOA. For most K awards, commitment of at least 75 percent or nine person months of time is required. NIH and other PHS agencies use the concept of person months as a metric for determining the percent of effort. For more information about calculating person months, see:

http://grants.nih.gov/grants/policy/person_months_faqs.htm.

2. Describe actions that will be taken to ensure this; e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year. (For example, describe the actions that will be taken to compensate for the reduction in clinic responsibilities of the candidate, e.g., hiring of additional staff). Describe the candidate's academic appointment, bearing in mind that it must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award. Describe the proportion of time currently available for the candidate's research experience and what the candidate's institutional responsibilities will be if an award is made.
3. Describe how the institution will provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed Research Plan.
4. Describe how the institution will provide appropriate time and support for any proposed mentor (s) and/or other staff consistent with the career development plan.

Signatures:

The institutional commitment must be dated and signed by the person who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement. If the candidate will be working away from the home institution, signatures from both the home and the host institution are required.

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

Attach this information as a PDF file.

Human Subjects Section

12. Protection of Human Subjects

Refer to Supplemental Instructions, Part II. Complete this section if you answered “yes” to the question “are human subjects involved?” on the Section G.220 - R&R Other Project Information Form. If you answered “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.

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.

13. Data Safety Monitoring Plan

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

Attach this information as a PDF file.

14. 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 G.200 - R&R Other Project Information form and the research does not fall under Exemption 4.

Also, please refer to Section G.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.

15. Inclusion of Children

Refer to Section 4.4 and 5.7 of the Supplemental Instructions, Part II. This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the Section G.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 Sections

16. Vertebrate Animals

Complete this section if you answered "yes" to the question "Are Vertebrate Animals Used?" on the Section G.220 - R&R Other Project Information Form, Vertebrate Animals.

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/VASchecklist.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.

17. 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 maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf.

If the activities proposed in your application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.4(f)(5), 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 at http://www.cdc.gov/od/sap/sap/exclusion.htm.

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 the 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 FOA, 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.

18. Consortium/Contractual Arrangements

If applicable, 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 SF 424 (R&R) form 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.*

Attach this information as a PDF file.

19. 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.

20. 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-16-012).

Attach this information as a PDF file.

Appendix

21. 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.

Citizenship

Please select the most appropriate response from the options provided. Other than for the K99/R00 and K43 award programs, or if specified differently in the FOA, the candidate must be a citizen or non-citizen national of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of award.

For those K award programs with a citizenship requirement, an individual who has applied for permanent residence and expects to have obtained such status prior to the time award may submit an application recognizing that no award will be made until legal verification of permanent resident status is provided. If a candidate's citizenship status changes after submission of the application, the new status should be reported in the candidate's Personal Profile in the eRA Commons. Before an award is issued, a permanent resident will be required to submit a notarized statement that a licensed notary has seen the candidate's current and valid Permanent Resident Card or some other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. as a permanent resident.

It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual candidate's visa will allow him/her to reside in the proposed research

training/career development setting for the period of time necessary to complete the approved career development program. Information may be requested by the NIH prior to issuance of an award.

The candidate must check the applicable box:

U.S. Citizen or Non-Citizen National:

Check this box if the candidate is a U.S. Citizen or Non-Citizen national. Non-Citizen nationals are people, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

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

Check this box if the candidate has been lawfully admitted for permanent residence; i.e., is in the possession of a current and valid permanent resident Card or other legal verification of such status. A notarized statement will be required as part of the pre-award process.

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

Check this box if the candidate currently holds a temporary U.S visa. This box is applicable only to specific programs that do not require U.S. citizenship or permanent residency; e.g., K99/R00. The NIH awarding component may request verifying information as part of the pre-award process.

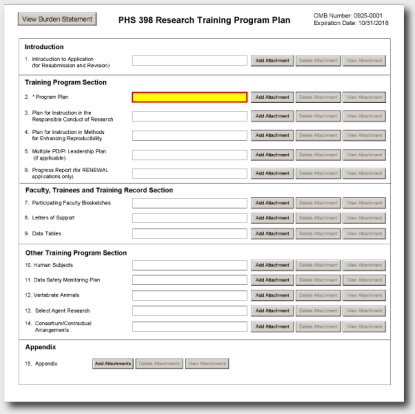
Non-U.S. Citizen Not Residing in the U.S.:

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

If the candidate is not a U.S citizen but has applied for permanent residence and expects to hold a permanent resident visa by the earliest possible start date of the award have obtained such status prior to the time of award, please also check this box at the bottom of the form indicating that permanent residence status is pending. A notarized statement will be required as a part of the pre-award process.

G.420 - PHS 398 Research Training Program Plan Form

The PHS 398 Research Training Program Plan Form is used only for Training applications and Multi-Project applications with a Training component. This form includes fields to upload several attachments including the program plan, faculty biosketches, and data tables.



View larger image

Quick Links

1. Introduction to Application (for Resubmission or Revision)
2. Program Plan
3. Plan for Instruction in the Responsible Conduct of Research
4. Plan for Instruction in Methods for Enhancing Reproducibility
5. Multiple PD/PI Leadership Plan
6. Progress Report (Renewal Applications Only)
7. Participating Faculty Biosketches
8. Letters of Support
9. Data Tables
10. Human Subjects
11. Data Safety Monitoring Plan
12. Vertebrate Animals
13. Select Agent Research
14. Consortium and Contractual Arrangements
15. Appendix

Before preparing the Research Training Program Plan, be sure to check the specific instructions in the Funding Opportunity Announcement (FOA) to which you are responding. Contact the appropriate PHS awarding component, which may have further advice or suggestions on completing your application, including the data tables mentioned below.

Note that there are page limits for certain sections. Follow the page limits for the Institutional Research Training and Career Development Applicants, Including Ruth L. Kirschstein NRSA Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. Please see NOT-OD-11-039 and NOT-OD-11-076.

The information provided in required data tables (Data Tables 1-8 described below) will not be counted toward the page limitation. These tables should be numbered consecutively and titled as shown. Additional tables required by the FOA or generated by the applicant may be included in the Research Training Program Plan, however, these tables will count as part of the page limit. Additional tables not specified in these instructions should be identified by letter, rather than number to avoid confusion with the sequentially numbered required tables.

The instructions for Data Tables 1-8 are located on the OER website at http://grants.nih.gov/grants/forms/datatables/forms-d.htm. Please read the Introduction to the Data Tables before beginning to prepare your application. This section includes important definitions that should be used consistently both in the Data Tables and in all other parts of the application. The Data Tables should be included in the application at the point indicated and should not be inserted in the narrative.

The Research Training Program Plan should include sufficient information to evaluate the proposed program, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

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)

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.

The Introduction is a required attachment for Resubmissions and Revisions. 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..

Training Program Section

2. Program Plan

The Program Plan must fit within the page limit for Institutional Research Training and Career Development Applicants, Including Ruth L. Kirschstein NRSA Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm.

A. Background

Provide the rationale for the proposed research training program, relevant background history, and the need for the research training proposed.

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

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program. If required by the FOA, complete and refer to the data reported in Tables 1-3, following the guidance below:

Table 1. Census of Participating Departments and Interdepartmental Programs.

Describe the organization of the proposed training program, the participating departments and interdepartmental programs, and the extent to which faculty, graduate students, and/or postdoctorates from those departments/interdepartmental programs participate in the programmatic activities to be supported by the training grant.

Table 2. Participating Faculty Members

Describe the distribution of participating faculty by academic rank, department or interdepartmental program, areas of research emphasis, and the rationale for the faculty selected to participate in the training grant. Analyze the data in terms of the overall experience of the faculty in training predoctorates and/or postdoctorates. Comment on the inclusion of faculty whose mentoring records may suggest limited, recent training experience at either training level (predoctoral or postdoctoral).

Table 3. Federal Institutional Research Training Grant and Related Support Available to Participating Faculty Members

Summarize the level of research training support at the institution. Comment on instances where the tabular data indicate that there may be substantial overlap of participating faculty.

Use this data to document the environment in which the proposed training program will take place.

B. Program Plan

NOTE: Applicants for institutional career development awards (e.g., K12s) must complete a Research Career Development Program Plan instead of the Training Program Plan. Refer to specific instructions in the FOA.

a. Program Administration.

Describe the Program Director's qualifications for providing leadership of the program, including relevant scientific background, current research areas, and experience in research training. Indicate the Program Director's percent effort in the proposed program.

Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

If multiple PD/PIs are proposed, explain in this section your rationale for how this will facilitate program administration. In addition, you must complete the Multiple PD/PI Leadership Plan.

b. Program Faculty.

Referring to the data presented in Table 2, Participating Faculty Members, describe each faculty member's research that is relevant to the program and indicate how trainees will participate in the research. Provide information on the extent to which participating faculty members have cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research.

Use this section to document the ability of the faculty to support the research activities of the proposed trainees, the training record of the faculty members, and the success of their trainees in generating publishable research results. For any proposed Program Faculty lacking research training experience, describe a plan to ensure successful trainee guidance by these individuals. Describe the criteria used to appoint and remove faculty as Program Faculty and to evaluate their participation

If required by the FOA, complete and refer to the data in Tables 4-5, following the guidance below:

Table 4. Research Support of Participating Faculty Members

Analyze the data in terms of total and average grant support. Additionally, comment on the inclusion of faculty without research grant support in the proposed training program and explain how the research of trainees who may work with these faculty members would be supported.

Table 5A. Publications of Those in Training: Predoctoral

Summarize these data, including, for example, the average number of publications, how many students published as first author, and how many students completed doctoral training without any first-author publication resulting from their graduate research.

Table 5B. Publications of Those in Training: Postdoctoral

Summarize these data, including, for example, the average number of papers published by postdoctorates, the number as first author, and the number of postdoctorates who completed training without any peer-reviewed publications.

Table 5C. Publications of Those in Training: Undergraduate

Summarize these data, including, for example, the average number of publications and how many students published their work.

For new applications, and if required by the FOA, see the instructions for Table 5A, 5B and/or 5C, as applicable, and list publications for trainees who are representative of those who would be appointed if the grant is awarded. For Renewal applications, these data constitute part of the Progress Report (see Progress Report below).

c. Proposed Training.

Describe the proposed training program. Indicate the training level(s) and number of trainees, the academic and research background needed to pursue the proposed training, and, as appropriate, plans to accommodate differences in preparation among trainees. For postdoctoral trainees, indicate the proposed distribution by degree (e.g., M.D., Ph.D.). Describe course work, research opportunities and the extent to which trainees will participate directly in research, activities designed to develop technical and/or professional skills, and the duration of training, i.e., usual period of time required to complete the training offered.

For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated and how they will relate to an individual trainee's experience.

For training programs that emphasize research training for clinicians, describe the interactions with basic science departments and scientists. Include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is expected for all postdoctoral trainees with health professional degrees. Describe fully any trainee’s access to and responsibility for patients, including time commitment.

Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the mentor and research problems are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Include detailed mentoring plans as appropriate.

d. Training Program Evaluation.

Describe an evaluation plan to review and determine the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the training program and to provide suggestions for program improvements. Specified evaluation metrics should be tied to the goals of the program. In addition, describe plans for assessing trainee’s career development and progression, including publications, degree completion, and post-training positions. Evaluation results are to be included in renewal (competing continuation) applications and as part of the Final Progress Report.

e. Trainee Candidates.

Describe, in general terms, the size and qualifications of the pool of trainee candidates including information about the types of prior clinical and research training and career level required for the program. Describe specific plans to recruit candidates and explain how these plans will be implemented (see also section on Recruitment Plan to Enhance Diversity). Describe the nomination and selection process to be used to select candidates who would be offered admission to the program and criteria for trainees’ reappointment to the program. If required by the FOA, complete Tables 6A and/or 6B Applicants, Entrants, and their Characteristics for the Past Five Years, and summarize the data in terms of the overall numbers of potential trainees, their credentials, characteristics, and eligibility for support, and enrollment trends.

f. Institutional Environment and Commitment to Training.

Include information in the application that documents the support and commitment of the applicant institution and participating units and departments to the goals of the proposed program. This could include, for example, space, shared laboratory facilities and equipment, funds for curriculum development, release time for the PD/PI and participating faculty, support for additional trainees in

the program, or any other creative ways to improve the environment for the establishment and growth of the research training program.

Include a signed letter, on institutional letterhead, that describes the applicant institution's commitment to the planned program (see instructions for Letters of Support, below). Institutions with ongoing research training, student development, or career development programs that receive external funding should explain what distinguishes the proposed program from existing ones at the same trainee level, how the programs will synergize, if applicable, whether trainees are expected to transition from one support program to another, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

g. Qualifications of Trainee Candidates and Admissions and Completion Records.

Describe the ability of the participating departments/programs to recruit and retain trainees through the completion of their training, the selectivity of the admissions process, and the success of the departments/programs in recruiting individuals from diverse backgrounds.

Discuss the quality and depth of the applicant pools, including both training grant eligible and non-training-grant eligible individuals; and the competitiveness of the program, referring to the data in Tables 6A and/or 6B, if applicable.

Report the number and characteristics of current program participants and their distribution by department and mentor. For renewal/revision applications, describe the selectivity of appointments to the training grant, as represented by the current program participants.

Use all of this information to justify the number of positions requested. If required by the FOA, complete and refer to the data in Tables 7-8:

Table 7, Appointments to the Training Grant for Each Year of the Current Project Period

Table 8A-D, Program Outcomes

C. Recruitment Plan to Enhance Diversity

The Recruitment Plan to Enhance Diversity must fit within the page limits for Institutional Research Training Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm.

Refer to Supplemental Instructions, Part III Section 1.19.

A Recruitment Plan to Enhance Diversity is required for all training grant activity codes except T34, T36, U2R, and all D-series activity codes Applications without a Recruitment Plan to Enhance Diversity will be considered incomplete and will not be reviewed.

New applications must include a description of plans to enhance recruitment, including the strategies that will be used to enhance the recruitment of trainees from underrepresented backgrounds and may wish to include data in support of past accomplishments. Renewal applications must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period (see also the Progress Report instructions, below).

History and Achievements.

Describe efforts to recruit trainees from Diversity groups A and B, as well as group C (when applicable), into the existing training program. If required by the FOA, refer to the data presented in Tables 6 and 7, as applicable, and use these data to document the success of the program in recruiting trainees who are under-represented and provide information on their support.

Proposed plans.

Describe steps to be taken during the proposed award period regarding the identification and recruitment of graduate students and postdoctorates from Diversity groups A and B, as well as group C (when applicable). Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school, and/or the university at large. In most cases, institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups.

Attach this information as a PDF file.

3. Plan for Instruction in the Responsible Conduct of Research

Follow the page limits for Plan for Instruction in the Responsible Conduct of Research in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm.

A plan for Instruction in the Responsible Conduct of Research (RCR) is required for all training grant activity codes except T36. Applications lacking a Plan for Instruction in the Responsible Conduct of Research will not be reviewed. Every trainee must receive instruction in the responsible conduct of research. See Supplemental Instructions, Part III Section 1.16 for information on the NIH Policy on Training in the Responsible Conduct of Research (RCR).

New applications must include a plan for instruction in the responsible conduct of research. The plan must address the five, required instructional components outlined in the NIH policy:

1. Format - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable);
2. Subject Matter - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics;
3. Faculty Participation - the role of the mentor(s) and other faculty involvement in the instruction;
4. Duration of Instruction - the total number of contact hours of instruction; and
5. Frequency of Instruction – instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed.

In addition, the plan must describe how participation in RCR instruction will be monitored.

Note that Senior Fellows may fulfill requirements for instruction in responsible conduct of research by participating as lecturers and discussion leaders.

In addition, Renewal applications must describe any changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current RCR instruction. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

Attach this information as a PDF file.

This is a required attachment unless the FOA specifies otherwise.

4. Plan for Instruction in Methods for Enhancing Reproducibility

Do not include an attachment in this field; this plan is not yet required.

5. Multiple PD/PI Leadership Plan

If you wish to submit a multiple PD/PI application, you must provide a Leadership Plan. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.

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

The emphasis in a training grant multiple PD leadership plan should be on how it will benefit the program and the trainees. A single Contact PD must be designated for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PDs. A single award will be made. Multiple PD plans should include reasonable numbers of PDs and each should be included for a specific purpose. Multiple-PD applications should not include all mentors of the training grant as PDs, except in unusual cases.

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.

For background information on the Multi-PD/PI initiative, see: http://grants.nih.gov/grants/multi_pi/index.htm.

Attach this information as a PDF file.

6. Progress Report (Renewal Applications Only)

Indicate the period covered and briefly describe the accomplishments of the training program. Describe any specific effects of this training program on curriculum and/or research directions. Describe how the funds provided under Training Related Expenses were used to benefit the program.

For each trainee supported during the period covered, include the following information, as applicable:

- Degrees working toward or held
- Mentor(s)
- Description of the trainee/scholar's research project and progress

- Coursework
- Conference presentations
- A description of the trainee/scholar's role in any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment, analyzed data, drafted paper)
- Fellowships or other support
- Workshops attended
- Career development activities

Indicate whether the institution utilizes Individual Development Plans (IDPs), and if so, describe how they were used in this reporting period to help manage the training and career development of the trainees/scholars (do not include actual IDPs). **This information is not required for AHRQ grantees.**

If required by the FOA, complete required Data Tables, following the guidance below:

- For current trainees and previous trainees appointed to the training grant and still in training, complete Table 5, Publications of Those in Training, and summarize the data presented in this table in the application. Note that a My Bibliography report of publications arising from work conducted by trainees while supported by the training grant is not required at the time of submission, but will be requested as Just-in-time (JIT) information prior to award
- Referring to Table 7, describe the utilization of awarded training positions. If any trainee positions were not filled, provide an explanation.
- Referring to relevant versions of Table 8 (e.g. 8A, 8B, 8C and/or 8D as appropriate), describe how training positions are used (i.e., distribution by mentor, year in program, years of support per trainee) and the success of the program in achieving the training objectives of the prior award period(s). If any postdoctoral trainee with a health professional degree was appointed to a Kirschstein-NRSA training grant for less than 2 years of research training, explain why. For past trainees, describe the extent of their current involvement in research, including research grant support received subsequent to completion of the training program.

Use the progress report narrative to provide information that is not readily presented in the required tables.

Renewal applications must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period. Information should be included on both successful and unsuccessful recruitment strategies.

Attach this information as a PDF file.

Faculty, Trainees, And Training Record

7. Participating Faculty Biosketches

Faculty Biosketches for participating faculty must follow the Instructions for a Biographical Sketch (refer Section G.240 - Senior/Key Person Profile (Expanded) Form), except that a personal statement

is not required for participating faculty. These should be attached as a single document to avoid having to upload large numbers of separate documents. However, the Biosketches of the Program Director and other Senior/Key Personnel should also be entered as described under SF424 (R&R) Section G.240 - Senior/Key Person Profile (Expanded) Form.

Attach this information as a PDF file.

8. Letters of Support

Attach appropriate letters here from all individuals confirming their roles in the project. Include a signed letter on institutional letterhead from a senior administration official that describes the applicant institution's commitment to the planned program. For consultants, letters should include rate/charge for consulting services.

The Program Director should check the FOA (particularly for non-NRSA programs) to determine if any program-specific letters of support are required.

Attach this information as a PDF file.

9. Data Tables

Instructions for Data Tables 1-8 mentioned above are located on the OER website at the following URL http://grants.nih.gov/grants/forms/datatables/forms-d.htm. These instructions include an Introduction to the Data Tables that provides instructions applicable to all tables, specific instructions for each table, and Sample Data Tables. The Sample Data Tables illustrate the kind of data to include in each table for Kirschstein-NRSA training grant applications. Be sure to choose the Instruction and Blank Data Table set that corresponds to the type of application you are submitting, e.g., New, Renewal, or Revision Application, and the kind of training to be provided, e.g., predoctoral only, postdoctoral only, pre and postdoctoral mixed, postdoctoral and short-term mixed. Instructions for use in other training grant, institutional career development, and research education grant applications will be included in relevant FOAs.

User-defined bookmarks in the Data Tables attachment will be retained in the assembled application image after submission to facilitate easy navigation between tables. Start each numbered table on a new page, and separately bookmark each table in the PDF attachment. Many PDF generators will automatically create bookmarks from text formatted using predefined Heading styles in Word.

Attach this information as a PDF file.

Other Training Program Section

10. Human Subjects

Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form.

If trainee participation in research involving human subjects is solely as part of other research projects and no portion of the Training Grant Award will be used to support this research, describe how the institution will ensure that trainees only participate in (a) exempt human subjects research or (b) non-exempt human subjects research that has IRB approval.

In training programs where trainees will design and conduct their own independent human subjects research, follow the instructions in Supplemental Instructions, Part II.

Attach this information as a PDF file.

11. Data Safety Monitoring Plan

Refer to Supplemental Instructions, Part II, and the FOA, if applicable. Complete this section if you answered "yes" to Item 2, Clinical Trials of the Cover Page Supplement Form.

Attach this information as a PDF file.

12. Vertebrate Animals

Complete this section if you answered "yes" to the question "Are Vertebrate Animals Used?" on the R&R Other Project Information Form, Vertebrate Animals.

Describe how the institution will ensure that trainees only participate in IACUC approved vertebrate animal research when:

- the training program uses live vertebrate animals only as part of other research project grants, and
- the Training Grant Award does not support the purchase, use, or husbandry of live vertebrate animals for this research.

In training programs where trainees will design and conduct their own independent vertebrate animal research, follow the instructions below:

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/VASchecklist.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.

13. Select Agent Research

If participating faculty proposed in the training program are conducting or plan to conduct research involving select agents in which trainees may participate, follow the instructions below

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.

14. Consortium and Contractual Arrangements

If applicable, describe any programmatic, fiscal, or administrative arrangements between the applicant organization and other participating organizations. See below:

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 G.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.*

Attach this information as a PDF file.

Appendix

15. 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 limitations of the Training Plan. 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.

Research publications of trainees and mentors are not normally included as part of the training grant applications, but are allowed. Note that only publications reflecting on the activities of the program as a whole may be included. When publications are allowed, appendix materials should be limited to those which are not publicly available, such as:

- Manuscripts and/or abstracts accepted for publication but not yet published.
- Published manuscripts and/or abstracts where a free, online, publicly available journal link is not available.

Publications that are publicly accessible must not be included in the appendix. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Progress Report section of the Research Training Program Plan, and/or in the Biographical Sketch.

Do not include unpublished theses or abstracts/manuscripts submitted but not yet accepted for publication.

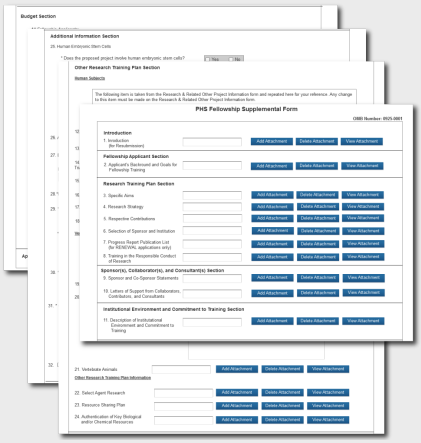
Some materials other than publications that are unique to training grant applications (but not typically included in research grant applications) may be included in the appendix. In general, the appendix may be used to provide samples of materials that are referred to in the body of the application, but are too cumbersome to include in the Research Training Program Plan without disrupting the narrative flow. Examples include:

- Syllabi for key courses, core courses and electives, including courses in Responsible Conduct of Research;
- Retreat, seminar series, and other program activity agendas, and schedules;
- Examples of forms used to document trainee progress and monitoring by the program;
- Examples of materials used in recruitment and particularly recruitment to enhance diversity of the applicant pool;
- Lists of meetings attended by students and their presentations; and
- Student biosketches.

As a reminder, tables other than the required Data Tables 1-8, must be incorporated into the page limit of the Research Training Program Plan. Follow the page limits for institutional training grants specified in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. These additional tables must not be included in the appendix materials.

G.430 - PHS Fellowship Supplemental Form

The PHS Fellowship Supplemental Form is used only for Fellowship applications. This form includes fields to upload several attachments including the specific aims, research strategy, and applicant background and goals section.



View larger image

Quick Links

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

It is strongly recommended that fellowship applicants and sponsors speak with a PHS Program Official for Institute or Center (IC)-specific guidance before preparing this application. These contacts are identified in tables associated with each FOA. In addition, a list of contacts specifically for extramural training at the NIH ICs can be found at https://researchtraining.nih.gov/tac-roster. For AHRQ, see http://www.ahrq.gov/funding/training-grants/contacts.html. Individuals always are encouraged to check these Web sites for the most current contact information.

The PHS Fellowship Supplemental Form 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. This section should be well-formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed in collaboration with your sponsor, but it should be written by you, the fellowship applicant.

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 (if Applicable)

1. Introduction to Application (Resubmission 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. 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.

The Introduction is a required attachment for Resubmissions and Revisions. 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.

Fellowship Applicant Section

2. Applicant's Background and Goals for Fellowship Training:

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

A. Doctoral Dissertation and Research Experience:

Summarize your research experience in chronological order. Advanced graduate students, who have (or will have) completed their comprehensive examinations by the time of award, must also include a narrative of their doctoral dissertation (may be preliminary). If you have no research experience, list other scientific experience. Do not list academic courses. In summarizing their research experience, Postdoctoral and Senior Fellowship applicants should include the areas studied and conclusions drawn. Postdoctoral fellowship applicants should also specify which areas of research were part of their thesis or dissertation and which, if any, were part of a previous postdoctoral project.

B. Training Goals and Objectives:

Describe your overall training goals for the duration of the fellowship, and explain how the proposed fellowship will enable the attainment of these goals. Identify the skills, theories,

conceptual approaches, etc. to be learned or enhanced during the award. As applicable, discuss how the proposed research will facilitate your transition to the next career stage.

C. Activities Planned Under this Award:

Describe, by year, the activities (research, coursework, etc.) you will be involved in during the proposed award and estimate the percentage of time to be devoted to each activity, based on a normal working day for a full-time fellow as defined by the sponsoring institution; the percentage should total 100 for each year. The activities planned under this award should be individually tailored and well integrated with your research project. Describe the skills and techniques that you intend to learn as well as any planned, non-research activities (e.g. those relating to professional development and clinical activities) during the award period. Provide a timeline detailing the proposed research training and related activities for the entire duration of the program

Attach this information as a PDF file.

Research Training Plan Section

A Research Training Plan is required for all types of individual F awards. The Research Training Plan is a major part of the Fellowship award plan. It is important to relate the research to the applicant's scientific career goals. Describe how the research, coupled with related training activities, will provide the experience, knowledge, and skills necessary to achieve the stated objectives of the Fellowship award. Explain the relationship between the applicant's research on the Fellowship award and the mentor's ongoing research program.

For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be managed; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The Research Training Plan of a Fellowship award is expected to be appropriate for, and tailored to the experience level of the applicant, and allow him/her to develop the skills needed for further career advancement; reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the focus of a Fellowship award research training plan. Although applicants for Fellowship awards are expected to write the Research Training Plan, the mentor should review a draft of the plan and discuss it in detail with the applicant. Review by other knowledgeable colleagues is also helpful. Although it is understood that Fellowship applications do not require the extensive detail usually incorporated into regular research grant applications, a fundamentally sound Research Training Plan should be provided.

3. Specific Aims

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

State precisely 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.

Attach this information as a PDF file.

4. Research Strategy

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Organize the Research Strategy section using the instructions provided below as guidance. Cite published experimental details within the text and provide the full reference in Section G.220 - R&R Other Project Information Form, Bibliography and References Cited.

A. Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

B. Innovation

- Fellowship applications should not include an Innovation section unless specified in the FOA.

C. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 23 (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.
- 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 22, 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.

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

Progress Report for Renewal Applications:

Renewal applications for individual fellowships are rare. You should consult with your program official before preparing such an application. In the rare instance that you are submitting a renewal application, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. 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 application. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in the Progress Report Publication List); do not include that information here.

Attach this information as a PDF file.

5. Respective Contributions

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Describe the collaborative process between you and your sponsor/co-sponsor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research.

Attach this information as a PDF file.

6. Selection of Sponsor and Institution

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

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

1. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the sponsoring organization, provide an explanation here.
2. Doctorate or Current Institution. (For postdoctoral and senior fellows only) Since training is expected to broaden a fellow's perspective, postdoctoral fellowship applicants requesting training at either their doctorate institution or at the institution where they have been training for

more than a year must explain why further training at that institution would be valuable. Individuals applying for Senior Fellowships who are requesting training at the institution at which they are employed should provide a similar explanation.

3. Foreign Institution. If you are proposing a research training experience at a foreign institution, show that the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection of a foreign institution should be described. If applicable, the need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.

Attach this information as a PDF file.

7. Progress Report Publication List (for RENEWAL applications only)

In the rare instance that you are submitting a renewal application, list the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

For NIH applications only, when citing articles that fall under the NIH Public Access Policy, http://publicaccess.nih.gov/, were authored or co-authored by the fellowship applicant and arose from NIH support or arose from AHRQ funding provided after 2/19/16 (see http://grants.nih.gov/grants/guide/notice-files/NOT-HS-16-008.html), or arose from AHRQ support after the publication date of the AHRQ public access policy, 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 NIH Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see F. Appendix below).

Attach this information as a PDF file.

8. Training in Responsible Conduct of Research

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. See Supplemental Instructions Supplemental Instructions, Part III 1.16 for information on the NIH Policy on Training in the Responsible Conduct of Research (RCR).

The plan must address the five, required instructional components outlined in the NIH policy:

1. Format - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable);
2. Subject Matter - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics;

3. Faculty Participation - the role of the mentor(s) and other faculty involvement in the instruction;
4. Duration of Instruction - the total number of contact hours of instruction; and
5. Frequency of Instruction - instruction must occur during each career stage and at least once every four years.

Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed. See also NOT-OD-10-019.

Senior fellows may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders.

Attach this information as a PDF file.

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

9. Sponsor and Co-Sponsor Statements

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA

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

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

A. Research Support Available

In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. If the sponsor's research support will end prior to the end of the proposed training period, the sponsor should provide a contingency plan for how the fellow's research will be supported. Include this information for any co-sponsor as well.

The role of the sponsor in the integrated research and training plan should be described. If a sponsor team is proposed, this plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively.

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

Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative and, for those five, provide information on time spent in the lab their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.

C. Training Plan, Environment, Research Facilities

Describe the research training plan that you have developed specifically for the Fellowship applicant. The training plan should be individualized for the applicant, keeping in mind the candidate's strengths and any gaps in needed skills, and should be designed to enhance both

research and clinical training (if applicable). Include items such as classes, seminars, opportunities for interaction with other groups and scientists and any professional skills development opportunities. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals. This information should be coordinated with information provided under Description of Institutional Environment and Commitment to Training.

For F30 applicants, the training plan should also provide opportunities to integrate clinical experiences during the research training component; a smooth transition to the clinical training component; and should have the potential to facilitate the applicant's transition to a residency or other program appropriate for his/her career goals, as applicable for the proposed clinical specialty.

For F31, F32, F33 applicants, the training plan should facilitate the applicant's transition to the next stage of his/her career.

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

Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.

E. Applicant's Qualifications and Potential for a Research Career

Describe how the Fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level, including how the research training plan, and your own expertise as the sponsor will assist in producing an independent researcher.

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

Attachments may be provided (if applicable) by collaborators, consultants, advisors, etc. Relevant information applicable to the fellow's planned research training and future goals may be provided by any contributor or advisor via an attachment.

Institutional Environment And Commitment To Training Section

11. Description of Institutional Environment and Commitment to Training

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (Section G.220 - R&R Other Project Information Form, Facilities and Other Resources), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations. This information should be coordinated with information provided under Sponsor and Co-Sponsor Statements, Training Plan, Environment, Research Facilities.

Additional Educational Information (required for F30 and F31 applications):

Describe the institution's dual-degree (F30) or graduate (F31) program in which the applicant is enrolled, e.g. the structure of the program, required milestones and their usual timing (number of courses, any teaching commitments, qualifying exams, etc.) and the average time to degree over the past 10 years. Describe the progress/status of the applicant in relation to the program's timeline, and the frequency and method by which the program formally monitors and evaluates a student's progress.

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

Note that a listing of the applicant's courses and grades must be included in the Fellowship Applicant Biographical Sketch, and NOT in this attachment.

Attach this information as a PDF file.

Other Research Training Plan Section

Human Subjects

Prefilled from the Research and Related Other Project Information form.

If activities involving human subjects are *not* planned at any time during the proposed project at any performance site, skip the remainder of the block and continue to Other Research Training Plan Sections.

If you have indicated "Yes" for Human Subjects involvement, consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing this section, and refer to Supplemental Instructions, Part II Section 4.1.

Human subjects requirements may apply even if you are obtaining specimens/data from collaborators or if you are subcontracting the human research to another organization. For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. The evaluation of the inclusion plans will be factored into the overall score that the SRG awards for scientific and technical merit of the application. Much of the information on the protection of human subjects that you are required to provide in the Fellowship application is identical to information that you will be required to provide for IRB review at your own institution.

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

12. Human Subjects Involvement Indefinite?

Check “Yes” if at the time of application plans to involve human subjects are unknown. If an award is made, you may not participate in human subjects research until an updated research training plan is submitted and approved by the awarding component. Such a plan must be developed in consultation with your sponsor. Certification of the date of IRB approval must also be submitted before the fellow can participate in human subjects research.

13. 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.

14. Agency-Defined Phase III Clinical Trial?

Check the “Yes” or “No” box 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, for the purpose of either evaluating an experimental intervention in comparison with a standard or control intervention or of comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. 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 are also included.

15. Protection of Human Subjects

Refer to Supplemental Instructions, Part II Section 4.1.

This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&R Other Project Information Form. If the answer is “No” to the question but the proposed research involves human specimens and/or data from subjects applicants must provide a justification in this section for the claim that no human subjects are involved.

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.

16. Data Safety Monitoring Plan

Complete this section if you answered “yes” to Item 13 in this form. Refer to Supplemental Instructions, Part II Section 4.1.

Attach this information as a PDF files.

17. Inclusion of Women and Minorities

This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form and the research does not fall under Exemption 4. Refer to Supplemental Instruction, Part II Section 4.1.

Attach this information as a PDF file.

18. Inclusion of Children

For applicants answering “Yes” to the question “Are human subjects involved” on the R&R Other Project Information Form and the research does not fall under Exemption 4, this section is required. Refer to Supplemental Instructions, Part II Section 4.1, 4.4 and 5.7

Attach this information as a PDF file.

Are Vertebrate Animals Used?

Prefilled from the Research and Related Other Project Information form.

Indicate 'No' and skip items 19 and 20 below if activities involving vertebrate animals are not planned at any time during the proposed project at any performance site.

19. Vertebrate Animals Use Indefinite?

Check “Yes” if plans for the involvement of vertebrate animals have not been finalized at the time of application making an IACUC review and approval not feasible at this stage. However, if an award is made, vertebrate animals may not be used until a verification of the date of IACUC approval has been submitted to the NIH IC or AHRQ.

20. Are animals euthanized?

Check "Yes" or "No" to indicate whether animals in the project are euthanized or not.

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 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.

21. Vertebrate Animals

This section is required for applicants answering "Yes" to the question "Are vertebrate animals involved?" on the 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/VASchecklist.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 following 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 below, 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.

Other Research Training Plan Information

Consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing Items 22 through 24.

22. Select Agent Research

Select agents are hazardous biological agents and toxins that have been identified by DHHS 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 maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf.

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 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, 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.

23. 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 Section 1.5.

Attach this information as a PDF file.

24. Authentication of Key Biological and/or Chemical Resources

Do not include an attachment in this field; this is not yet required.

Additional Information Section

25. Human Embryonic Stem Cells

Indicate "Yes" if the proposed research involves human embryonic stem cells. See http://stemcells.nih.gov/info/basics/pages/basics3.aspx for a definition of human embryonic stem cells. If the proposed project involves human embryonic stem cells, list in this section the 4-digit NIH Registration Number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry found at: http://grants.nih.gov/stem_cells/registry/current.htm. If a specific stem cell line cannot be referenced at the time of application submission, check the box provided to indicate that one from the registry will be used.

26. Alternate Phone Number

Enter an alternate phone number (e.g., cell phone) where the fellowship applicant can be reached on matters relating to this application for fellowship support. This should be a different number than provided in the PD/PI contact information in the SF424 (R&R) Form.

27. Degree Sought During Proposed Award

Complete if applicable. If you will be working toward a degree while receiving fellowship support, select the type of degree from the drop-down menu. If the degree is not on the drop down menu, please select "Other" and indicate the type of degree in the space provided.

28. Field of Training for Current Proposal

Select a single Field of Training code from the drop-down menu that best describes the proposed area of research training. This information is used for reporting purposes only and is not used for study

section assignments.

29. Current or Prior Kirschstein-NRSA Support?

If “Yes”, identify the current and/or prior Kirschstein-NRSA support from the drop down menu, up to four entries. Define level of support as either predoctoral or postdoctoral level (not the level of experience). The type of support is either individual fellowship or institutional research training grant. Enter the start and end dates (if known) of the support (month, day, and year) and the grant number (if known) of the current and/or prior support (e.g., T32 GM123456 or F31 HL345678).

An individual cannot receive more than 5 years of cumulative predoctoral Kirschstein-NRSA support and 3 years cumulative postdoctoral Kirschstein-NRSA support (the total of Institutional Grants and Individual Fellowships) without a waiver from the awarding component. The awarding components have different policies on waiving the statutory limits on support. Therefore, the fellowship applicant must request a waiver from the probable funding IC before requesting a period of support that would exceed these limits. The fellow’s sponsor and a sponsoring institution official must endorse the request, and it must include justification and specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their awarding IC Program Officer before submitting a waiver request. It is important to read carefully the applicable FOA that may have an overall approval to exceed these limits (e.g., the F30) programs allow for up to 6 years of predoctoral support).

Promptly report to the awarding component to which this application is assigned any additional NRSA support received while this application is pending.

30. Applications for Concurrent Support?

Check the appropriate answer, indicating “Yes” if the fellowship applicant has applied or will be applying for other support that would run concurrently with the period covered by this application. Include the type, dates, source(s) and amount in the attachment document, if applicable. The fellowship applicant must promptly report to the NIH IC to which this application is assigned, or AHRQ, any support resulting from other such applications.

Attach this information as a PDF file.

31. Citizenship

To be eligible for a Kirschstein-NRSA Individual Fellowship (F30, F31, F32, F33), the fellowship applicant must be a U.S. citizen, a non-citizen national, or have been lawfully admitted to the U.S. for permanent residence before the award is issued. Individuals on temporary student visas are not eligible for NRSA support.

If the fellowship applicant is applying for a non-NRSA fellowship program supported by the NIH, for which citizenship or permanent residency is not required (e.g., Fogarty International Center programs), the fellowship applicant must have in his/her possession a valid visa allowing him/her to remain in the U.S. (or in a foreign research training setting, if applicable) long enough to be productive on the proposed fellowship project. It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual fellowship applicant’s visa will allow him/her to

reside in the proposed research training setting for the period of time necessary to complete the proposed fellowship.

U.S. Citizen or Non-Citizen National:

Check this box if the applicant is a U.S. citizen or non-citizen national. Non-citizen nationals are people, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

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

Check this box if the applicant has been lawfully admitted for permanent residence; i.e., is in the possession of a current and valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status.

Before the award is issued, a permanent resident will be required to submit a notarized statement that a licensed notary has seen the fellowship applicant's valid Permanent Resident Card (USCIS Form I-551) or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

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

Check this box if the fellowship applicant is a non-citizen holding a temporary U.S. visa.

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

32. Change of Sponsoring Institution

Indicate if this application is being submitted with a change of sponsoring institution. If the box is checked, the name of the former sponsoring institution must be provided.

Budget Section

All Fellowship Applicants:

1. Tuition and Fees

All fellowship applicants should list the estimated costs of tuition and fees. Postdoctoral and senior fellowship applicants should list the costs associated with courses planned that support the research training experience and are identified and described in the attachment for the Applicant's Background and Goals for Fellowship Training, under "Activities Planned Under This Award." If no tuition and fees are being requested, check the box provided.

With the exception of senior fellowship applicants, no additional budget information is required. The final stipend and institutional allowance will be determined at the time of award.

In accordance with NIH Guide NOT-OD-10-073, funds to offset the costs of health insurance (self or family, as appropriate) are included in the standard Institutional Allowance, and not to be requested as part of Tuition and Fees.

Senior Fellowship Applicants Only:

2. Present Institutional Base Salary

Senior fellowship applicants must provide their present base salary and indicate the period of time on which the salary is determined (e.g., academic year of 9 months, full-time 12 months, etc. The number may not be more than 12, but may include a decimal indicating partial months (e.g., 9.5).

3. Stipend/ Salary During First Year of Proposed Fellowship

A. Federal Stipend Requested:

Fellowship applicants must insert the stipend being requested for the initial period of support and the number of months.

B. Supplementation from other sources:

Fellowship applicants should enter the anticipated amount and the length of time associated with the amount. Enter also the type of supplementation expected (e.g., salary, sabbatical leave, etc.) and the source of such funding.

Appendix

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

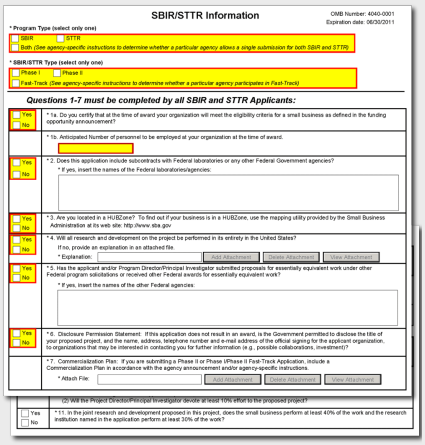
For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section.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

G.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 G.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.

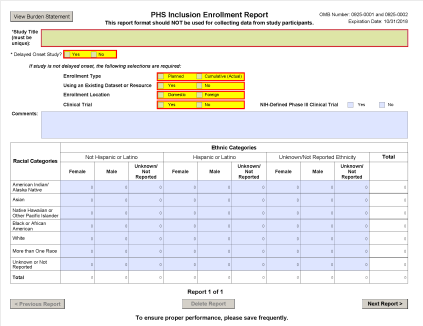
11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

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.

G.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 unique)

* Delayed Onset Study? Yes No

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

Enrollment Type: Planned Cumulative (Actual)

Using an Existing Dataset or Resource: Yes No

Enrollment Location: Domestic Foreign

Clinical Trial: Yes No

NIH-Defined Phase III Clinical Trial: Yes No

Comments:

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

Report 1 of 1

< Previous Report | Delete Report | Next Report >

To ensure proper performance, please save frequently.

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:

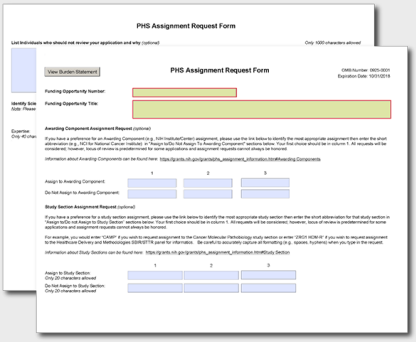
Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) 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.

G.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).


PHS Assignment Request Form

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.

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 Modular Budget Form
- PHS 398 Training Budget Form
- PHS 398 Training Subaward Budget Attachment(s) Form
- PHS Additional Indirect Cost
- PHS 398 Research Plan
- PHS 398 Career Development Award Supplemental Form
- PHS 398 Research Training Program Plan Form
- PHS Fellowship Supplemental Form
- SBIR/STTR Information Form
- PHS Inclusion Enrollment Report
- PHS Assignment Request Form

SF 424 (R&R) Form

OMB Number: 4040-0001

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE
State Application Identifier

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

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

2. DATE SUBMITTED
Applicant Identifier

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

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

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

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

8. TYPE OF APPLICATION:
☐ New ☐ Resubmission
☐ Renewal ☐ Continuation ☐ Revision

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

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

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

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

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

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

15. ESTIMATED PROJECT FUNDING

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

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

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

☐ **I agree**

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

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

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

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

Signature of Authorized Representative: Completed on submission to Grants.gov

Date Signed: Completed on submission to Grants.gov

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

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

PHS 398 Cover Page Supplement

PHS 398 Cover Page Supplement

View Burden Statement

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

1. Human Subjects Section

Clinical Trial? ☐ Yes ☐ No

*Agency-Defined Phase III Clinical Trial? ☐ Yes ☐ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☐ No

If "**Yes**" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines? ☐ Yes ☐ No

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

3. *Program Income Section

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

☐ Yes ☐ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)
X		

Add

4. Human Embryonic Stem Cells Section

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

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

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

Cell Line(s) (Example: 0004):

X

Add

PHS 398 Cover Page Supplement

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: Yes ☐ No ☐

If "**Yes**" then answer the following:

*Previously Reported: Yes ☐ No ☐

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:
*First Name:
Middle Name:
*Last Name:
Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Other Project Information Form

RESEARCH & RELATED Other Project Information

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

1. Are Human Subjects Involved? ☐ Yes ☐ No
   1.a. If YES to Human Subjects
   Is the Project Exempt from Federal regulations? ☐ Yes ☐ No
   If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
   If no, is the IRB review Pending? ☐ Yes ☐ No
   IRB Approval Date:
   Human Subject Assurance Number:
2. Are Vertebrate Animals Used? ☐ Yes ☐ No
   2.a. If YES to Vertebrate Animals
   Is the IACUC review Pending? ☐ Yes ☐ No
   IACUC Approval Date:
   Animal Welfare Assurance Number:
3. Is proprietary/privileged information included in the application? ☐ Yes ☐ No
4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No
4.b. If yes, please explain:
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No
4.d. If yes, please explain:
5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No
5.a. If yes, please explain:
6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No
6.a. If yes, identify countries:
6.b. Optional Explanation:
7. Project Summary/Abstract Add Attachment | Delete Attachment | View Attachment
8. Project Narrative Add Attachment | Delete Attachment | View Attachment
9. Bibliography & References Cited Add Attachment | Delete Attachment | View Attachment
10. Facilities & Other Resources Add Attachment | Delete Attachment | View Attachment
11. Equipment Add Attachment | Delete Attachment | View Attachment
12. Other Attachments Add Attachments | Delete Attachments | View Attachments

Project/Performance Site Location(s) Form

OMB Number: 4040-0010

Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

Project/Performance Site Location 1

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

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

Additional Location(s) Add Attachment Delete Attachment View Attachment

Senior/Key Persons Profile (Expanded)

OMB Number: 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

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

Credential, e.g., agency login:

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

Degree Type:
Degree Year:

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

PROFILE - Senior/Key Person 1

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

Credential, e.g., agency login:

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

Degree Type:
Degree Year:

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

Delete Entry Next Person

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

R&R Budget Form

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001

ORGANIZATIONAL DUNS: Enter name of Organization:

Budget Type: ☐ Project ☐ Subaward/Consortium Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)

Project Role:

Additional Senior Key Persons: Add Attachment Delete Attachment View Attachment

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total Other Personnel

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

C. Equipment Description

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

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment Delete Attachment View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees — Total Participant/Trainee Support Costs	

F. Other Direct Costs

		Funds Requested ($)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
	Total Other Direct Costs	

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	

J. Fee

Funds Requested ($)

K. Budget Justification

(Only attach one file.) Add Attachment Delete Attachment View Attachment

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

R&R Subaward Budget Attachment(s) Form

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

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1		Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2		Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4		Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5		Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6		Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7		Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8		Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9		Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10		Add Attachment	Delete Attachment	View Attachment
11) Please attach Attachment 11		Add Attachment	Delete Attachment	View Attachment
12) Please attach Attachment 12		Add Attachment	Delete Attachment	View Attachment
13) Please attach Attachment 13		Add Attachment	Delete Attachment	View Attachment
14) Please attach Attachment 14		Add Attachment	Delete Attachment	View Attachment
15) Please attach Attachment 15		Add Attachment	Delete Attachment	View Attachment
16) Please attach Attachment 16		Add Attachment	Delete Attachment	View Attachment
17) Please attach Attachment 17		Add Attachment	Delete Attachment	View Attachment
18) Please attach Attachment 18		Add Attachment	Delete Attachment	View Attachment
19) Please attach Attachment 19		Add Attachment	Delete Attachment	View Attachment
20) Please attach Attachment 20		Add Attachment	Delete Attachment	View Attachment
21) Please attach Attachment 21		Add Attachment	Delete Attachment	View Attachment
22) Please attach Attachment 22		Add Attachment	Delete Attachment	View Attachment
23) Please attach Attachment 23		Add Attachment	Delete Attachment	View Attachment
24) Please attach Attachment 24		Add Attachment	Delete Attachment	View Attachment
25) Please attach Attachment 25		Add Attachment	Delete Attachment	View Attachment
26) Please attach Attachment 26		Add Attachment	Delete Attachment	View Attachment
27) Please attach Attachment 27		Add Attachment	Delete Attachment	View Attachment
28) Please attach Attachment 28		Add Attachment	Delete Attachment	View Attachment
29) Please attach Attachment 29		Add Attachment	Delete Attachment	View Attachment
30) Please attach Attachment 30		Add Attachment	Delete Attachment	View Attachment

PHS 398 Modular Budget

View Burden Statement

PHS 398 Modular Budget

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

Budget Period: 1

Start Date: End Date: Next Period

A. Direct Costs

Funds Requested ($)

Direct Cost less Consortium Indirect (F&A) 0.00

Consortium Indirect (F&A)

Total Direct Costs 0.00

B. Indirect (F&A) Costs

Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base ($)	Funds Requested ($)

Add Additional Indirect Cost

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect (F&A) Rate Agreement Date

Total Indirect (F&A) Costs

C. Total Direct and Indirect (F&A) Costs (A + B)

Funds Requested ($) 0.00

Add Period

Cumulative Budget Information

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period	$	0.00
Section A, Total Consortium Indirect (F&A) for Entire Project Period	$	
Section A, Total Direct Costs for Entire Project Period	$	0.00
Section B, Total Indirect (F&A) Costs for Entire Project Period	$	
Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period	$	0.00

2. Budget Justifications

? Personnel Justification		Add Attachment	Delete Attachment	View Attachment
? Consortium Justification		Add Attachment	Delete Attachment	View Attachment
? Additional Narrative Justification		Add Attachment	Delete Attachment	View Attachment

PHS 398 Training Budget

View Burden Statement

PHS 398 TRAINING BUDGET, Period 1

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

Organizational DUNS: Budget Type: Project Subaward/Consortium

See Cumulative

Organization Name:

Start Date: End Date:

A. Stipends, Tuition/Fees

Number of Trainees

Full Time	Short Term		Stipends Requested ($)	Tuition/Fees Requested ($)
		Undergraduate:		
		Number Per Stipend Level: First-Year/Soph. Junior/Senior		
		Predoctoral: Single Degree		
		Dual Degree		
		Total Predoctoral		
		Postdoctoral: *Number Per Stipend Level:* 0 1 2 3 4 5 6 7		
		Non-degree Seeking		
		Degree Seeking		
		Total Postdoctoral		
		Other:		
		Totals:		
		Total Stipends + Tuition/Fees Requested		

B. Other Direct Costs

	Funds Requested ($)
Trainee Travel	
Training Related Expenses	
Total Direct Costs from R&R Budget Form (if applicable)	
Consortium Training Costs (if applicable)	
Total Other Direct Costs Requested	

C. Total Direct Costs Requested (A + B)

D. Indirect (F&A) Costs

	Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base	Funds Requested ($)
1.				
2.				
			Total Indirect (F&A) Costs Requested	

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

F. Budget Justification ? Add Attachment Delete Attachment View Attachment

Add Period

Previous

PHS 398 TRAINING BUDGET, Cumulative Budget

A. Stipends, Tuition/Fees

		Stipends Requested ($)	Tuition/Fees Requested ($)
Undergraduate:			
Predoctoral:	Single Degree		
	Dual Degree		
	Total Predoctoral		
Postdoctoral:	Non-Degree Seeking		
	Degree Seeking		
	Total Postdoctoral		
Other:			
	Totals:		
	Total Stipends + Tuition/Fees Requested		

B. Other Direct Costs

	Funds Requested ($)
Trainee Travel	
Training Related Expenses	
Total Direct Costs from R&R Budget Form (if applicable)	
Consortium Training Costs (if applicable)	
Total Other Direct Costs Requested	

C. Total Direct Costs Requested (A + B)

D. Total Indirect Costs Requested

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

Training Subaward Budget Attachment(s) Form

View Burden Statement

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

TRAINING SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions:

This form allows you to attach a PHS 398 Training Budget form for each subaward/consortium associated with your application. Use the "Click here to extract the PHS 398 Training Subaward Attachment" button to extract a blank copy of the PHS 398 Training Budget form, complete the form in accordance with the agency instructions, and attach the completed form using one of the "Add Attachment" buttons.

Click here to extract the PHS 398 Training Subaward Attachment

Important:

Attach Training Subaward Budget forms, using the blocks below. Remember that the files you attach must be PHS 398 Training Budget PDF forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

Attach Training Subaward Budget 1		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 2		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 3		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 4		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 5		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 6		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 7		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 8		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 9		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 10		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 11		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 12		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 13		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 14		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 15		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 16		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 17		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 18		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 19		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 20		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 21		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 22		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 23		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 24		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 25		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 26		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 27		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 28		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 29		Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 30		Add Attachment	Delete Attachment	View Attachment

PHS Additional Indirect Cost

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

PHS Additional Indirect Costs - Budget Period 1

Delete Period

ORGANIZATIONAL DUNS: **Enter name of Organization:**

Budget Type: Project Subaward/Consortium **Budget Period: 1** *** Start Date:** *** End Date:**

Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)

Add Additional Indirect Cost

Total Indirect Costs

Budget Justification

(Only attach one file.) Add Attachment Delete Attachment View Attachment

Add Period

PHS Additional Indirect Costs - Cumulative Budget

	Totals ($)
Indirect Costs	

PHS 398 Research Plan

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

PHS 398 Career Development Award Supplemental Form

PHS 398 Career Development Award Supplemental Form

View Burden Statement

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

Introduction

1. Introduction to Application (RESUBMISSION)		Add Attachment	Delete Attachment	View Attachment

Candidate Section

2. Candidate Information and Goals for Career Development		Add Attachment	Delete Attachment	View Attachment

Research Plan Section

3. Specific Aims		Add Attachment	Delete Attachment	View Attachment
4. * Research Strategy		Add Attachment	Delete Attachment	View Attachment
5. Progress Report Publication List (for RENEWAL applications only)		Add Attachment	Delete Attachment	View Attachment
6. Training in the Responsible Conduct of Research		Add Attachment	Delete Attachment	View Attachment

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring		Add Attachment	Delete Attachment	View Attachment

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s)		Add Attachment	Delete Attachment	View Attachment
9. Letters of Support from Collaborators, Contributors, and Consultants		Add Attachment	Delete Attachment	View Attachment

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment		Add Attachment	Delete Attachment	View Attachment
11. Institutional Commitment to Candidate's Research Career Development		Add Attachment	Delete Attachment	View Attachment

Human Subject Sections

12. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
13. Data Safety Monitoring Plan		Add Attachment	Delete Attachment	View Attachment
14. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
15. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment

PHS 398 Career Development Award Supplemental Form

Other Research Plan Sections

16. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
17. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
18. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
19. Resource Sharing		Add Attachment	Delete Attachment	View Attachment
20. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

Appendix

21. Appendix — Add Attachments | Delete Attachments | View Attachments

* Citizenship

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

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

☐ With a Permanent U.S. Resident Visa

☐ With a Temporary U.S. Visa

☐ Not Residing in the U.S.

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

PHS 398 Research Training Program Plan

View Burden Statement

PHS 398 Research Training Program Plan

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

Introduction

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

Training Program Section

2. * Program Plan — Add Attachment | Delete Attachment | View Attachment
3. Plan for Instruction in the Responsible Conduct of Research — Add Attachment | Delete Attachment | View Attachment
4. Plan for Instruction in Methods for Enhancing Reproducibility — Add Attachment | Delete Attachment | View Attachment
5. Multiple PD/PI Leadership Plan (if applicable) — Add Attachment | Delete Attachment | View Attachment
6. Progress Report (for RENEWAL applications only) — Add Attachment | Delete Attachment | View Attachment

Faculty, Trainees and Training Record Section

7. Participating Faculty Biosketches — Add Attachment | Delete Attachment | View Attachment
8. Letters of Support — Add Attachment | Delete Attachment | View Attachment
9. Data Tables — Add Attachment | Delete Attachment | View Attachment

Other Training Program Section

10. Human Subjects — Add Attachment | Delete Attachment | View Attachment
11. Data Safety Monitoring Plan — Add Attachment | Delete Attachment | View Attachment
12. Vertebrate Animals — Add Attachment | Delete Attachment | View Attachment
13. Select Agent Research — Add Attachment | Delete Attachment | View Attachment
14. Consortium/Contractual Arrangements — Add Attachment | Delete Attachment | View Attachment

Appendix

15. Appendix — Add Attachments | Delete Attachments | View Attachments

PHS Fellowship Supplemental Form

PHS Fellowship Supplemental Form

OMB Number: 0925-0001

Introduction

1. Inroduction (for Resubmission)		Add Attachment	Delete Attachment	View Attachment

Fellowship Applicant Section

2. Applicant's Backround and Goals for Fellowship Training		Add Attachment	Delete Attachment	View Attachment

Research Training Plan Section

3. Specific Aims		Add Attachment	Delete Attachment	View Attachment
4. Research Strategy		Add Attachment	Delete Attachment	View Attachment
5. Respective Contributions		Add Attachment	Delete Attachment	View Attachment
6. Selection of Sponsor and Institution		Add Attachment	Delete Attachment	View Attachment
7. Progress Report Publication List (for RENEWAL applications only)		Add Attachment	Delete Attachment	View Attachment
8. Training in the Responsible Conduct of Research		Add Attachment	Delete Attachment	View Attachment

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

9. Sponsor and Co-Sponsor Statements		Add Attachment	Delete Attachment	View Attachment
10. Letters of Support from Collaborators, Contributors, and Consultants		Add Attachment	Delete Attachment	View Attachment

Institutional Environment and Commitment to Training Section

11. Description of Institutational Environment and Commitment to Training		Add Attachment	Delete Attachment	View Attachment

Other Research Training Plan Section

Human Subjects

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

Are Human Subjects Involved? ☐ Yes ☐ No

12. Human Subjects Involvement Indefinite? ☐ Yes ☐ No

13. Clinical Trial? ☐ Yes ☐ No

14. Agency-Defined Phase III Clinical Trial? ☐ Yes ☐ No

15. Protection of Human Subjects [ ] Add Attachment | Delete Attachment | View Attachment

16. Data Safety Monitoring Plan [ ] Add Attachment | Delete Attachment | View Attachment

17. Inclusion of Women and Minorities [ ] Add Attachment | Delete Attachment | View Attachment

18. Inclusion of Children [ ] Add Attachment | Delete Attachment | View Attachment

Vertebrate Animals

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

Are Vertebrate Animals Used? ☐ Yes ☐ No

19. Vertebrate Animals Use Indefinite? ☐ Yes ☐ No

20. Are 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 a scientific justification [ ]

21. Vertebrate Animals [ ] Add Attachment | Delete Attachment | View Attachment

Other Research Training Plan Information

22. Select Agent Research [ ] Add Attachment | Delete Attachment | View Attachment

23. Resource Sharing Plan [ ] Add Attachment | Delete Attachment | View Attachment

24. Authentication of Key Biological and/or Chemical Resources [ ] Add Attachment | Delete Attachment | View Attachment

Additional Information Section

25. Human Embryonic Stem Cells

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

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

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

Cell Line(s) (Example:0004):

Add

26. Alternate Phone Number

27. Degree Sought During Proposed Award:

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

28.*Field of Training for Current Proposal

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

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

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

Add

30. *Applications for Concurrent Support? ☐ Yes ☐ No

If yes, please describe in an attached file Add Attachment Delete Attachment View Attachment

31. * Citizenship

U.S. Citizen ☐ U.S. Citizen or Non-Citizen National

Non-U.S. Citizen ☐ With a Permanent U.S. Resident Visa ☐ With a Temporary U.S. Visa

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

32. ☐ Change of Sponsoring Institution

Name of Former Institution

Budget Section

All Fellowship Applicants:

1. * Tuition and Fees: ☐ None Requested ☐ Funds Requested

Year 1

Year 2

Year 3

Year 4

Year 5

Year 6 *(if applicable)*

Total Funds Requested:

Senior Fellowship Applicants Only

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

3. Stipends/Salary During First Year of Proposed Fellowship

a. Federal Stipend Requested: Amount | Number of Months

b. Supplementation from other sources: Amount | Number of Months

Type (sabbatical leave, salary, etc.)

Source

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*					