Annotated Form Set for
NIH Small Business (SBIR/STTR) Grant Applications

FORMS-E Series – Application due dates on/after January 25, 2018

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NOTES:

- The Funding Opportunity Announcement (FOA) and associated application guide remain the official documents for defining application requirements. This resource is meant to complement, not replace, those documents.
- NIH application packages include a subset of the forms included in this resource. You will only need to complete the forms provided to you with a specific FOA.
- The actual display of the forms depends on your submission method (e.g., downloadable forms, ASSIST). The same forms, form fields and guidance apply regardless of submission option even if the display is slightly different.
- This resource is for FORMS-E application packages, see Do I Have the Right Forms for My Application?
- Registration in multiple systems is needed prior to submission, see Get Registered! Can take 6 weeks – start early!
- Don't forget to periodically check the Related Notices section of the FOA for any updates to instructions or policies since the opportunity was posted.
- The blue annotations throughout this resource represent processing notes and eRA system business rule checks (i.e., validations).

National Institutes of Health
Office of Extramural Research

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

1. TYPE OF SUBMISSION

☐ Pre-application ☐ Application ☐ Changed/Corrected Application

Use Application for first submission attempt for due date.

Do not use Pre-application unless specifically noted in FOA.

Use Changed/Corrected when submitting again to Grants.gov to correct eRA identified errors/ warnings.

2. DATE SUBMITTED | **Applicant Identifier**

3. DATE RECEIVED BY STATE | **State Application Identifier**

4. a. Federal Identifier

b. Agency Routing Identifier

c. Previous Grants.gov Tracking ID

If New (box 8), leave blank unless otherwise instructed in FOA. If Resubmission, Renewal or Revision (box 8), use institute and serial # of previous NIH grant/application # (e.g., use CA987654 from 1R41CA987654-01).

If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678).

5. APPLICANT INFORMATION

Organizational DUNS:

Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations. Must be 9 or 13 digits; no letters or special characters.

Legal Name:

Department: Division:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Small business must be in the U.S.

Must provide zip+4 for all zip codes.

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:

Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used.

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

7. TYPE OF APPLICANT: Please select one of the following

Must select "Small Business" for SBIR/STTR applications.

Other (Specify):

Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

Once "Small Business" is selected, Organization Type is active.

8. TYPE OF APPLICATION:

See application guide for definitions.

☐ 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:

NIH will assign CFDA post-submission.

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

Phase II should have the same title as awarded Phase I. If Revision (box 8), provide exact title (including punctuation and spacing) as seen in eRA Commons for awarded grant. Limited to 200 characters.

12. PROPOSED PROJECT:

Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). See application guide for additional details.

Generally, SBIR Phase I awards do not exceed 6 months and STTR Phase I awards do not exceed one year. Generally, SBIR and STTR Phase II awards do not exceed two years.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

PD/PI first/last name should match name on file for Commons ID provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) form.

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

Manually enter amounts.

Guideline: SBIR/STTR
Phase I - $150K
Phase II - $1M

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:

SBIR/STTR: Check "No - Program is not covered by E.O.

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**

See the NIH Grants Policy Statement for more information: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm

**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:

Authorized Organization Representative (AOR) in Grants.gov must have signature authority for the organization. The electronic signature of the submitting AOR is recorded with submission.

In eRA Commons individuals with signature authority are called Signing Officials (SOs).

Signature of Authorized Representative **Date Signed**

20. Pre-application

21. Cover Letter Attachment

Cover letter is posted as a separate document in eRA Commons and is not part of the assembled application image. Content is only made available to select agency staff. Do not include assignment or review request information in your cover letter (use PHS Assignment Request Form for assignment and review information instead).

PHS 398 Cover Page Supplement

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

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☐ No

Answer required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.

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

Up to 1000 characters.

2. *Program Income Section

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

☐ Yes ☐ No

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

*Budget Period	*Anticipated Amount ($)	*Source(s)
		Up to 150 characters.

The number of program income budget periods must be less than or equal to the number of periods included in the budget form.

3. Human Embryonic Stem Cells Section

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

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

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

Cell Line(s) (Example: 0004):

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Provide up to 200 cell lines.

4. Inventions and Patents Section (for Renewal applications)

SBIR/STTR: Only applies to Phase II applications.

*Inventions and Patents: Yes ☐ No ☐

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

*Previously Reported: Yes ☐ No ☐

PHS 398 Cover Page Supplement

5. Change of Investigator/Change of Institution Section

Change of Investigator not allowed for Revision applications.

☐ 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:

RESEARCH & RELATED Other Project Information

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

If Human Subjects = Yes, additional information is required on the PHS Human Subjects and Clinical Trials Information form.

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. If YES to Human Subjects

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

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

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

IRB Approval Date:

IRB Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

Human Subject Assurance Number:

If Human Subjects = Yes, the Human Subject Assurance Number or the text 'None' must be provided exactly as it appears in eRA Commons institution profile.

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

If Vertebrate Animals = Yes, additional attachments are required in the PHS 398 Research Plan or equivalent form.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

IACUC Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

Animal Welfare Assurance Number:

If Vertebrate Animals = Yes, the Animal Welfare Assurance Number or the text 'None' must be provided. Type the number exactly as it appears in eRA Commons Institution Profile.

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:

If 4a is Yes, then 4b is required. Up to 55 characters.

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

4.d. If yes, please explain:

If 4c is Yes, then 4d is required. Up to 55 characters.

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

5.a. If yes, please explain:

If 5 is Yes, then 5a is required. Up to 55 characters.

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

6.a. If yes, identify countries:

If 6 is Yes, then 6a is required. Up to 55 characters.

6.b. Optional Explanation:

Up to 55 characters.

7. Project Summary/Abstract

Succinct project summary of proposed work. Typically 30 lines or less; system will give error if over 1 page. If awarded this information becomes public. Do not include proprietary or confidential information.

8. Project Narrative

Typically 2-3 sentence statement of public health relevance; system will give error if over 1 page.

9. Bibliography & References Cited

Required unless otherwise noted in opportunity. Not system enforced.

View Attachment

10. Facilities & Other Resources

Required unless otherwise noted in opportunity. Not system enforced.

View Attachment

11. Equipment

Required unless otherwise noted in opportunity. Not system enforced.

View Attachment

12. Other Attachments

Add Attachments | Delete Attachments | View Attachments

Only provide Other Attachments when requested in the funding opportunity announcement text or application guide. Field accommodates multiple attachments.

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.

DO NOT check box. NIH only accepts applications from registered organizations.

Organization Name:

DUNS Number:

DUNS required and enforced by NIH. Must be 9 or 13 digits; no letters or special characters.

* 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:

Optional for non-primary sites. Helps facilitate application processing, so include it if you have it.

List all performance sites, including any foreign sites. Provide a list of resources available from each site in the Facilities and Resources attachment on the R&R Other Project Information form. Describe any consortium/contractual arrangements in the Consortium/Contractual Arrangements attachment on the PHS 398 Research Plan form or equivalent form.

* 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

Form accommodates up to 300 sites. Use the Additional Locations attachment to include any sites over 300. See Additional Performance Site Format page at: https://grants.nih.gov/grants/forms/additional-performance-site.htm

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:
* 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:

Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.

VALID ERA COMMONS USERNAME MUST BE SUPPLIED. Contact PD/PI must be affiliated in Commons with applicant organization. Commons account designated on this form should not have both the PI and SO roles (if PD/PI also serves as SO, use a separate account for SO functions).

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

Project Role will default to PD/PI and must remain PD/PI (do not edit).

Degree Type:
Degree Year:

***Attach Biographical Sketch**
Attach Current & Pending Support

Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm

Only provide Current & Pending Support if specifically requested in FOA. May be requested later in pre-award process as Just-In-Time data.

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:

Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.

For multiple PD/PI applications, you must use the PD/PI role and provide the eRA Commons username in the Credential field for all PD/PIs. If multiple PD/PIs are included, the Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form is required.

*** 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

Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm

Delete Entry Next Person

Can collect data for 100 Sr/Key personnel (including PD/PI). Option to provide attachment for additional Sr/Key info is available after the 100 entries are made. See Additional Senior/Key Person Profiles format page at: https://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm.

To ensure proper per ... application, close the Adobe Reader, and reopen it.

Form only included in small business funding opportunity announcements.

SBIR/STTR Information

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

*** Agency to which you are applying (select only one)**

☐ DOE ☐ HHS ☐ USDA ☐ Other:

Check HHS for all NIH, CDC, and FDA submissions.

*** SBC Control ID:** Required. *(This 9 digit code is obtained from the Small Business Administration)*

*** Program Type (select only one)** Must select SBIR or STTR (not Both).

☐ SBIR ☐ STTR

☐ Both *(See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)*

*** Application Type (select only one)**

Not valid for STTR. Not valid for HHS (NIH, CDC, FDA).

☐ Phase I ☐ Phase II ☐ Fast-Track ☐ Direct Phase II ☐ Phase IIA ☐ Phase IIB

☐ Commercialization Readiness Program *(See agency-specific instructions to determine application type participation.)*

Check opportunity for allowable Application Types.

Phase I Letter of Intent Number:

Leave blank. N/A for HHS (NIH, CDC, FDA) submissions.

*** Agency Topic/Subtopic:** Optional.

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? Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award. Required.
☐ Yes ☐ No	* 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? Selection required.
☐ Yes ☐ No	* 1d. Is your small business a Faculty or Student-Owned entity? Selection required.
☐ Yes ☐ No Selection required.	* 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: Required if Yes. Up to 250 characters. Cannot include if No.
☐ 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 Selection required.
☐ Yes ☐ No Selection required.	* 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: Required if No. Cannot include if Yes. Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No Selection required.	* 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: Required if Yes. Up to 250 characters. Cannot include if No.
☐ 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 email address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? Selection required.
	* 7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase I/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * Attach File: Required for Phase II, Direct Phase II, Phase IIB, Phase1/Phase II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.

SBIR/STTR Information

SBIR-Specific Questions: Answers only required for SBIR applications.

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: Answers only required for STTR applications.

Questions 10 - 12 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 - 12 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?
	* 12. Provide DUNS Number of non-profit research partner for STTR. Enter the DUNS or DUNS+4 number of the non-profit research partner for the STTR applicant.

Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

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

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

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

Are Human Subjects Involved? ☐ Yes ☐ No

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

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

Information populated from R&R Other Project Information form.

If No to Human Subjects

Answer required and system enforced when human subjects is No.

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

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

Required if Yes to human specimens/data question.

Add Attachment | Delete Attachment | View Attachment

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

When human subjects is No, applicants answer a single question, provide associated attachment (as applicable), and are done with the form unless instructed in announcement to include Other Requested Information attachment.

If Yes to Human Subjects

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

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Check Application Guide and opportunity instructions to determine if attachment is needed.

Click here to extract the Human Subject Study Record Attachment

Stu

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

Atta

1) Please attach Human Subject Study 1

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.

Multiple delayed onset studies can be grouped in a single record.

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

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.

Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form.

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

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

* Always required field

Section 1 - Basic Information

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

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

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

Answer required and system enforced.

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

If Study Exempt is Yes, must provide exemption number.

1.4. * Clinical Trial Questionnaire

Answers to questionnaire required and system enforced.

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

1.4.a. Does the study involve human participants?	☐ Yes	☐ No
1.4.b. Are the participants prospectively assigned to an intervention?	☐ Yes	☐ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	☐ Yes	☐ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	☐ Yes	☐ No

If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.

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

Optional, provide NCT# if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application.

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required and system enforced unless study is exemption 4. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits **Minimum Age** Dropdown: Years, Months **Maximum Age** Dropdown: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

If "N/A (No Limit)" selected, do not provide numerical min/ max age.

2.4. Inclusion of Women, Minorities, and Children Required and system enforced unless study is exemption 4.

2.5. Recruitment and Retention Plan Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.6. Recruitment Status Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

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

2.7. Study Timeline Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.8. Enrollment of First Subject Date: MM/DD/YYYY. Dropdown: Anticipated, Actual

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

Inclusion Enrollment Report

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

Answer required and system enforced.

2. * Enrollment Location Type ☐ Domestic ☐ Foreign

Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

3. Enrollment Country(ies)

Multi-select from list of countries.

4. Enrollment Location(s)

5. Comments

Up to 500 characters.

Planned

Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

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

Cumulative (Actual)

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

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

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects Required and system enforced. Add Attachment | Delete Attachment | View Attachment

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

☐ Yes ☐ No ☐ N/A Answer required and system enforced. "N/A" is only a valid option for fellowship, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies. View Attachment

3.3. Data and Safety Monitoring Plan Required and system enforced for CT study. Optional for HS study. View Attachment

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

☐ Yes ☐ No Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

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

Section 4 - Protocol Synopsis

You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Brief Summary

Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.2. Study Design All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

4.2.a. Narrative Study Description

Up to 32,000 characters.

4.2.b. Primary Purpose Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; and Device Feasibility

Health Services Research
Basic Science
Device Feasibility
Other

4.2.c. Interventions Up to 20 Interventions allowed.

Intervention Type	
Name	Up to 200 characters.
Description	Up to 1,000 characters.

Dropdown list: Drug (including placebo); Device (including sham); Biological/Vaccine; Procedure/Surgery; Radiation; Behavioral (e.g., Psychotherapy, Lifestyle Counseling); Genetic (including gene transfer, stem cell and recombinant DNA); and Dietary Supplement (e.g., vitamins, minerals)

Dietary Supplement (e.g., vitamins, minerals)
Combination Product
Diagnostic Test
Other

Early Phase 1 (or Phase 0)
Phase 1
Phase 1/2

4.2.d. Study Phase Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and Other

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

4.2.e. Intervention Model Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.

Factorial
Sequential
Other

4.2.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/ Outcomes Assessor check boxes.

4.2.g. Allocation Dropdown list: N/A; Randomized; and Non-randomized

4.3. Outcome Measures At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

Name	Up to 255 characters.
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

4.4. Statistical Design and Power Required and system enforced for CT study unless otherwise noted in opportunity. Add Attachment | Delete Attachment | View Attachment

4.5. Subject Participation Duration Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.6. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No Answer required and system enforced for CT study unless otherwise noted in opportunity.

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

Required and system enforced if Yes. Add Attachment | Delete Attachment | View Attachment

4.7. Dissemination Plan Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

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

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.

Optional form in most grant application packages.

PHS Assignment Request Form

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

The PHS Assignment Request Form will be posted as a separate document in eRA Commons and is not part of the assembled application image. Content is only made available to select agency staff.

Funding Opportunity Number:

Pre-populated from announcement information.

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

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

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

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

Study Section Assignment Request *(optional)*

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

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

	First Choice	Second Choice	Third Choice
Assign to Study Section: *Only 20 characters allowed*			
Do Not Assign to Study Section: *Only 20 characters allowed*			

PHS Assignment Request Form

List individuals who should not review your application and why *(optional)* *Only 1000 characters allowed*

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

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

Provide DUNS for the organization whose budget is reflected on this form.

Only the primary applicant organization should use Budget Type of Project.

RESEARCH & RELATED BUDGET - Budget Period 1

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

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

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

For STTR, there must be at least one Research Institution budget with type Subaward/Consortium for each year of the Project budget.

A. Senior/Key Person

Every Sr/Key listed must have measurable effort in either Calendar Months or a combination of Academic and Summer Months.

PD/PI must be listed as a Sr/Key with measurable effort in every budget period.

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

Project Role: PD/PI

Base Salary can be left blank for submission, but is required prior to award.

STTR: If the PD/PI is an employee of the Research Institution (RI), then their information should be entered on the RI subaward budget page and the amounts on the Project budget can be blank or $0.

SBIR: There must be a Sr/Key entry with a role of PD/PI for each budget year of the Project budget.

Additional Senior Key Persons: Add Attachment Delete Attachment View Attachment

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

If more than 8 Sr/Key, use attachment and enter total funds requested for additional Sr/Key persons.

Total Senior/Key Person

B. Other Personnel

Aggregate information should be provided in section B and explained in Budget Justification.

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						

You can name up to 6 additional Project Role categories. Once data for the first user-defined Project Role is entered, you will have the option to add another. If you run out of additional categories combine categories in a single row and explain what was included in the Budget Justification.

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 ($)
	Once equipment data is entered, you will be able to add up to 9 more rows to this section for a total of 10 equipment items.	

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 — Generally, Foreign Travel Costs do not apply to SBIR/STTR applications.	
	Total Travel Cost	

E. Participant/Trainee Support Costs

Only complete this section if requested to do so in the funding opportunity announcement.

		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	

Subaward/Consortium/Contractural Costs are not pre-populated. Include both Direct and Indirect costs.

G. Direct Costs

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

H. Indirect Costs

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

Applicants without a NIH-negotiated Indirect Cost Rate can request up to 40% in both Phase I and Phase II.

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 ($)
A Fee cannot be entered for a Subaward/Consortium budget.	

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	

L. Budget Justification

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

Budget Justification is required and must cover all budget periods.

RESEARCH & RELATED BUDGET - Cumulative Budget

Cumulative Budget is system generated based on budget period data provided.

		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		
Section K, Total Costs and Fee (I + J)		

The actual look of this form will vary based on your submission method. The Grants.gov PDF version is shown here. In ASSIST, use the Add Optional Form option to add the R&R Subaward Budget tab to your application.

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

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.

The sum of all subaward budgets (e.g., those attached separately on this form and those provided as part of the budget justification), must be included in Line F.5 Subawards/Consortium/ Contractual Costs of the parent budget.

If submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section K of the R&R Budget form. This form should only be used in conjunction with the R&R Budget form.

Do not include the Subaward Budget Attachment form with applications that use the PHS 398 Modular Budget form.

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

PHS 398 Research Plan

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

Introduction

1. Introduction to Application (for Resubmission and Revision applications) — Limited to 1 page. Required for Resubmission and Revision applications. Attachment

Research Plan Section

2. Specific Aims — Required. Limited to 1 page. Add Attachment | Delete Attachment | View Attachment
3. *Research Strategy — Required: Phase I SBIR/STTR: limited to 6 pages. Phase II: SBIR/STTR and Fast Track SBIR/STTR: limited to 12 pages. w Attachment
4. Progress Report Publication List — Add Attachment | Delete Attachment | View Attachment

Other Research Plan Section

5. Vertebrate Animals — Required if Vertebrate Animals is Yes on the Other Project Information form. Delete Attachment | View Attachment
6. Select Agent Research — Add Attachment | Delete Attachment | View Attachment
7. Multiple PD/PI Leadership Plan — Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form. ent
8. Consortium/Contractual Arrangements — Add Attachment | Delete Attachment | View Attachment
9. Letters of Support — Required for R36 applications. Add Attachment | Delete Attachment | View Attachment
10. Resource Sharing Plan(s) — Add Attachment | Delete Attachment | View Attachment
11. Authentication of Key Biological and/or Chemical Resources — Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.

Appendix

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

Appendices are not allowed for SBIR or STTR Phase 1 applications (except RFAs).

DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the FOA as allowed or required.

Allows for up to 10 appendices. See Application Guide and announcement for restrictions.

Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.