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

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

Table of Contents

<table>
<thead>
<tr>
<th>Forms</th>
<th>Page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R)</td>
<td>2</td>
</tr>
<tr>
<td>PHS 398 Cover Page Supplement</td>
<td>4</td>
</tr>
<tr>
<td>R&amp;R Other Project Information</td>
<td>6</td>
</tr>
<tr>
<td>Project/Performance Site Location(s)</td>
<td>7</td>
</tr>
<tr>
<td>R&amp;R Senior/Key Person Profile (Expanded)</td>
<td>8</td>
</tr>
<tr>
<td>SBIR/STTR Information</td>
<td>9</td>
</tr>
<tr>
<td>PHS Human Subject and Clinical Trial Form</td>
<td>11</td>
</tr>
<tr>
<td>PHS Assignment Request Form</td>
<td>17</td>
</tr>
<tr>
<td>R&amp;R Budget</td>
<td>19</td>
</tr>
<tr>
<td>R&amp;R Subaward Budget Attachment(s) Form</td>
<td>23</td>
</tr>
<tr>
<td>PHS 398 Research Plan</td>
<td>24</td>
</tr>
</tbody>
</table>

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., 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).
<table>
<thead>
<tr>
<th>Section</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. TYPE OF SUBMISSION</td>
<td>Use Application for first submission attempt for due date. Use Changed/Corrected when submitting again to Grants.gov to correct eRA identified errors/warnings. Do not use Pre-application unless specifically noted in FQA.</td>
</tr>
<tr>
<td>2. DATE SUBMITTED</td>
<td>Applicant Identifier</td>
</tr>
<tr>
<td>3. DATE RECEIVED BY STATE</td>
<td>State Application Identifier</td>
</tr>
<tr>
<td>4. a. Federal Identifier</td>
<td>If New (box 8), leave blank. If Revision/Resubmission/Renewal (box 8), use Institute and serial # of previous NIH grant/application # (e.g., use CA987654 from 1R41CA987654-01). For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX).</td>
</tr>
<tr>
<td>4. b. Agency Routing Identifier</td>
<td>If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678).</td>
</tr>
<tr>
<td>5. APPLICANT INFORMATION</td>
<td>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.</td>
</tr>
<tr>
<td>6. EMPLOYER IDENTIFICATION (EIN) or (TIN):</td>
<td>Must provide zip+4 for all zip codes.</td>
</tr>
<tr>
<td>7. TYPE OF APPLICANT:</td>
<td>Small business must be in the U.S.</td>
</tr>
<tr>
<td>8. TYPE OF APPLICATION:</td>
<td>Please select one of the following</td>
</tr>
<tr>
<td>9. NAME OF FEDERAL AGENCY:</td>
<td>NIH will assign CFDA post-submission.</td>
</tr>
<tr>
<td>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</td>
<td></td>
</tr>
<tr>
<td>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</td>
<td>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.</td>
</tr>
<tr>
<td>12. PROPOSED PROJECT:</td>
<td>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.</td>
</tr>
<tr>
<td>13. CONGRESSIONAL DISTRICT OF APPLICANT</td>
<td></td>
</tr>
</tbody>
</table>

**Updated:** April 18, 2019
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:
   - PROGRAM IS NOT COVERED BY E.O. 12372; OR
   - PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

b. NO

I agree

See the NIH Grants Policy Statement for more information: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_44.1_public_policy_requirements_and_objectives.htm

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

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).

19. Authorized Representative

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

20. Pre-application

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).
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
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: 

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Updated: April 18, 2019
1. Are Human Subjects Involved?
   1.a. If YES to Human Subjects
      - Is the Project Exempt from Federal regulations? [ ] Yes [ ] No
      - If yes, check appropriate exemption number. [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] 8
      - If no, is the IRB review Pending? [ ] Yes [ ] No
      - IRB Approval Date:
      - Human Subject Assurance Number:
      - Exemptions 7 and 8 can be used for due dates on/after January 25, 2019.

2. Are Vertebrate Animals Used?
   2.a. If YES to Vertebrate Animals
      - Is the IACUC review Pending? [ ] Yes [ ] No
      - IACUC Approval Date:
      - Animal Welfare Assurance Number:
      - 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.

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.

10. Facilities & Other Resources
    - Required unless otherwise noted in opportunity. Not system enforced.

11. Equipment
    - Required unless otherwise noted in opportunity. Not system enforced.

12. Other Attachments
    - Only provide Other Attachments when requested in the funding opportunity announcement text or application guide. Field accommodates multiple attachments.
### Project/Performance Site Location

**Project/Performance Site Primary Location**

- **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)**

- **Organization Name:**
- **DUNS Number:**
- **Street1:**
- **Street2:**
- **City:**
- **County:**
- **State:**
- **Province:**
- **Country:** USA: UNITED STATES
- **ZIP / Postal Code:**
- **Project/Performance Site Congressional District:**

**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

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td>* First Name: Middle Name:</td>
</tr>
<tr>
<td>Last Name</td>
<td>* First Name: Middle Name:</td>
</tr>
<tr>
<td>Position/Title</td>
<td>Department:</td>
</tr>
<tr>
<td>Organization Name</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
</tr>
<tr>
<td>Street1</td>
<td>*</td>
</tr>
<tr>
<td>Street2</td>
<td>*</td>
</tr>
<tr>
<td>City</td>
<td>County/Parish: Province:</td>
</tr>
<tr>
<td>State</td>
<td>*</td>
</tr>
<tr>
<td>Country</td>
<td>* Zip / Postal Code:</td>
</tr>
<tr>
<td>Phone Number</td>
<td>Fax Number:</td>
</tr>
<tr>
<td>E-Mail</td>
<td>Credential, e.g., agency login:</td>
</tr>
<tr>
<td>Project Role</td>
<td>PD/PI. Project Role will default to PD/PI and must remain PD/PI (do not edit).</td>
</tr>
<tr>
<td>Other Project Role Category</td>
<td>Required. Limited to 5 pages. Format page, instructions and samples: <a href="http://grants.nih.gov/grants/forms/biosketch.htm">http://grants.nih.gov/grants/forms/biosketch.htm</a></td>
</tr>
<tr>
<td>Degree Type</td>
<td></td>
</tr>
<tr>
<td>Degree Year</td>
<td></td>
</tr>
<tr>
<td>Attach Biographical Sketch</td>
<td>Only provide Current &amp; Pending Support if specifically requested in FOA. May be requested later in pre-award process as Just-In-Time data.</td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td></td>
</tr>
</tbody>
</table>

#### Profile - Senior/Key Person 1

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td>* First Name: Middle Name:</td>
</tr>
<tr>
<td>Last Name</td>
<td>* First Name: Middle Name:</td>
</tr>
<tr>
<td>Position/Title</td>
<td>Department:</td>
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<tr>
<td>Organization Name</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
</tr>
<tr>
<td>Street1</td>
<td>*</td>
</tr>
<tr>
<td>Street2</td>
<td>*</td>
</tr>
<tr>
<td>City</td>
<td>County/Parish: Province:</td>
</tr>
<tr>
<td>State</td>
<td>*</td>
</tr>
<tr>
<td>Country</td>
<td>* Zip / Postal Code:</td>
</tr>
<tr>
<td>Phone Number</td>
<td>Fax Number:</td>
</tr>
<tr>
<td>E-Mail</td>
<td>Credential, e.g., agency login:</td>
</tr>
<tr>
<td>Project Role</td>
<td>*</td>
</tr>
<tr>
<td>Other Project Role Category</td>
<td>Required. Limited to 5 pages. Format page, instructions and samples: <a href="http://grants.nih.gov/grants/forms/biosketch.htm">http://grants.nih.gov/grants/forms/biosketch.htm</a></td>
</tr>
<tr>
<td>Degree Type</td>
<td></td>
</tr>
<tr>
<td>Degree Year</td>
<td></td>
</tr>
<tr>
<td>Attach Biographical Sketch</td>
<td></td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td></td>
</tr>
</tbody>
</table>

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.

Updated: April 18, 2019

FORMS-E Series

Page 8 of 24


### 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:

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

* 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)*

* Application Type (select only one)

- [ ] 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.)*

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Required/Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td>Required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).</td>
</tr>
<tr>
<td>1b. Anticipated Number of personnel to be employed at your organization at the time of award.</td>
<td>Required.</td>
</tr>
<tr>
<td>1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>1d. Is your small business a Faculty or Student-Owned entity?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>If yes, insert the names of the Federal laboratories/agencies:</td>
<td></td>
</tr>
<tr>
<td>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: <a href="http://www.sba.gov">http://www.sba.gov</a></td>
<td>Selection required.</td>
</tr>
<tr>
<td>4. Will all research and development on the project be performed in its entirety in the United States?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>If no, provide an explanation in an attached file.</td>
<td></td>
</tr>
<tr>
<td>Explanation:</td>
<td>Required if No. Cannot include if Yes.</td>
</tr>
<tr>
<td>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?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>If yes, insert the names of the other Federal agencies:</td>
<td>Required if Yes. Up to 250 characters. Cannot include if No.</td>
</tr>
<tr>
<td>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)?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase III/IV Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.</td>
<td>Required for Phase II, Direct Phase II, Phase IIB, Phase I/Phase II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.</td>
</tr>
</tbody>
</table>

Updated: April 18, 2019
### 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.**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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:</td>
<td>Add Attachment</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?</td>
<td></td>
</tr>
</tbody>
</table>

### 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.**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
| * 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

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

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

Answer required and system enforced when human subjects is No.

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

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

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

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.

Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.

Study Title

Anticipated Clinical Trial?

Justification

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.
Study Record: PHS Human Subjects and Clinical Trials Information

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. Exemptions 7 and 8 can be used for due dates on/after January 25, 2019.

1.4. * Clinical Trial Questionnaire
   - If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.
     - Yes ☐ No ☐
     - Yes ☐ No ☐
     - Yes ☐ No ☐
     - Yes ☐ No ☐

1.4.a. Does the study involve human participants?
1.4.b. Are the participants prospectively assigned to an intervention?
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

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.

2.3. Age Limits
   - Minimum Age
   - Maximum Age

2.4. Inclusion of Women, Minorities, and Children
   - Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

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.

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
   - 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 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.

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Total</th>
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<td>Asian</td>
<td></td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
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<td>0</td>
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<tr>
<td>White</td>
<td></td>
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<tr>
<td>More than One Race</td>
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<td>0</td>
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<tr>
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</tbody>
</table>

Updated: April 18, 2019
<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Unknown/Not Reported</th>
<th>Total</th>
</tr>
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<td>American Indian/Alaska Native</td>
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<td>Total</td>
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</tr>
</tbody>
</table>
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Add Attachment  |  Delete Attachment  |  View Attachment

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

☐ Yes  ☐ No  ☐ N/A  

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

Add Attachment  |  Delete Attachment  |  View Attachment

Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies.

3.3. Data and Safety Monitoring Plan

Add Attachment  |  Delete Attachment  |  View Attachment

Required and system enforced for CT study. Optional for HS study.

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

☐ Yes  ☐ No

3.5. Overall Structure of the Study Team

Add Attachment  |  Delete Attachment  |  View Attachment

Optional.

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

4.2.c. Interventions

Up to 20 Interventions allowed.

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Up to 200 characters.</td>
<td>Up to 1,000 characters.</td>
</tr>
</tbody>
</table>

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 a NIH-defined Phase III clinical trial?

☐ Yes  ☐ No

4.2.e. Intervention Model

Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.

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

4.2.f. Masking

☐ Yes  ☐ No

☑ Participant  ☐ Care Provider  ☐ Investigator  ☐ Outcomes Assessor

Updated: April 18, 2019

FORMS-E Series
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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Up to 255 characters.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Dropdown list: Primary; Secondary; and Other</td>
</tr>
<tr>
<td>Time Frame</td>
<td>Up to 255 characters.</td>
</tr>
<tr>
<td>Brief Description</td>
<td>Up to 999 characters.</td>
</tr>
</tbody>
</table>

4.4. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

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.

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

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

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:

Funding Opportunity Title: Pre-populated from announcement information.

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

Assign to Awarding Component:  [First Choice]  [Second Choice]  [Third Choice]

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

Assign to Study Section:  [First Choice]  [Second Choice]  [Third Choice]

Do Not Assign to Study Section:  [Only 20 characters allowed]

First Choice

Second Choice

Third Choice

Updated: April 18, 2019
# 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*

**Expertise:**

Only 40 characters allowed

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
## RESEARCH & RELATED BUDGET - Budget Period 1

**Budget Type:**
- [ ] Project
- [ ] Subaward/Consortium

**Start Date:** __________  
**End Date:** __________ 

**Budget Period:** 1

**Expiration Date:** 10/31/2019

**OMB Number:** 4040-0001

---

### ORGANIZATIONAL DUNS:

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

**Enter name of Organization:** __________

---

### A. Senior/Key Person

For STTR, there must be at least one Research Institution budget with type Subaward/Consortium for each year of the Project budget. Every Sr/Key listed must have measurable effort in either Calendar Months or a combination of Academic and Summer Months.

**Prefix**

**First**

**Middle**

**Last**

**Suffix**

**Base Salary ($)**

**Cal. Acad. Sum.**

**Requested Salary ($)**

**Fringe Benefits ($)**

**Funds Requested ($)**

**PD/PI**

**Add Attachment**

**Delete Attachment**

**View Attachment**

**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:

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

---

### B. Other Personnel

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

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
<td>Cal.</td>
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<td></td>
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<tr>
<td></td>
<td>Graduate Students</td>
<td>Acad.</td>
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<td></td>
<td>Undergraduate Students</td>
<td>Sum.</td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
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<td></td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Equipment item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

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

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

Foreign Travel Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

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

Total Travel Cost

### E. Participant/Trainee Support Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

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

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>If including &quot;Technical Assistance&quot; type the string as requested. Systems will only pick up an exact match to the letters and spacing of the string (not case specific). Can be in field 8, 9, or 10.</td>
<td></td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

### G. Direct Costs

**Total Direct Costs (A thru F)**

### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

**Total Indirect Costs**

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

### I. Total Direct and Indirect Costs

**Total Direct and Indirect Institutional Costs (G + H)**

### J. Fee

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

### K. Total Costs and Fee

**Total Costs and Fee (I + J)**

### L. Budget Justification

Budget Justification is required and must cover all budget periods.

Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.
### Section A, Senior/Key Person
Total Number Other Personnel

### Section B, 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)

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

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

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.
# PHS 398 Research Plan

## Introduction
1. **Introduction to Application**
   - Limited to 1 page. Required for Resubmission and Revision applications.

## Research Plan Section
2. **Specific Aims**
   - Required. Limited to 1 page.

3. **Research Strategy**

4. **Progress Report Publication List**

## Other Research Plan Section
5. **Vertebrate Animals**
   - Required if Vertebrate Animals is Yes on the Other Project Information form.

6. **Select Agent Research**

7. **Multiple PD/PI Leadership Plan**
   - Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.

8. **Consortium/Contractual Arrangements**

9. **Letters of Support**
   - Required for R36 applications.

10. **Resource Sharing Plan(s)**

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**
   - 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.