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).
APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

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

2. DATE SUBMITTED
   - Applicant Identifier

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.

5. APPLICANT INFORMATION
   - Legal Name:
   - Department:
   - Division:
   - Street1:
   - Street2:
   - City:
   - County / Parish:
   - State:
   - Country: USA: UNITED STATES
   - Zip / Postal Code:
   - Prefix:
   - First Name:
   - Middle Name:
   - Last Name:
   - Suffix:
   - Position/Title:
   - Phone Number:
   - Fax Number:
   - Email:

Person to be contacted on matters involving this application:

Prefix: First Name: Middle Name: Last Name: Suffix: Position/Title: 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):
   - Must select "Small Business" for SBIR/STTR applications.

7. TYPE OF APPLICANT:
   - Small Business Organization Type
   - Women Owned
   - Socially and Economically Disadvantaged

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

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

Revision, mark appropriate box(es).

Revison, 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:

   - 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.
15. ESTIMATED PROJECT FUNDING
Manually enter amounts.

- Total Federal Funds Requested
- Total Non-Federal Funds
- Total Federal & Non-Federal Funds
- Estimated Program Income

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

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:
  - SBIR/STTR: Check "No - Program is not covered by E.O."
  - PROGRAM IS NOT COVERED BY E.O. 12372; OR
  - PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW
- b. NO

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)

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

19. Authorized Representative

20. Pre-application

21. Cover Letter Attachment

*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.
1. Vertebrate Animals Section
Are vertebrate animals euthanized? □ Yes □ No
If "Yes" to euthanasia
Is method consistent with American Veterinary Medical Association (AVMA) guidelines? □ Yes □ No
If "No" to AVMA guidelines, describe method and provide scientific justification

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)

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):

4. Inventions and Patents Section (for Renewal 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:

[ ]
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.  ☐  ☐  ☐  ☐  ☐
   If no, is the IRB review Pending?  Yes ☐  No ☐
   IRB Approval Date: ____________________________
   Human Subject Assurance Number: ____________________________
   If Human Subjects = Yes, additional information is required on the PHS Human Subjects and Clinical Trials Information form.

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

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 ☐
   b. If yes, please explain:  If 4a is Yes, then 4b is required. Up to 55 characters.

5. Is the research performance site designated, or eligible to be designated, as a historic place?  Yes ☐  No ☐
   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 ☐
   a. If yes, identify countries:  If 6 is Yes, then 6a is required. Up to 55 characters.
   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 Primary Location

Organization Name: [ ]

DUNS Number: [ ]

* Street1: [ ]

Street2: [ ]

* City: [ ]

County: [ ]

* State: [ ]

* Province: [ ]

* Country: [ ]

* ZIP / Postal Code: [ ]

* Project/Performance Site Congressional District: [ ]

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.

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

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.

Additional Location(s)

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
### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
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<tbody>
<tr>
<td>* Last Name:</td>
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<td>Position/Title:</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>
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<td>* Street1:</td>
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<td>Street2:</td>
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<tr>
<td>* City:</td>
<td>County/ Parish:</td>
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<td>* State:</td>
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<td>Country:</td>
<td>USA: UNITED STATES</td>
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<td>* Phone Number:</td>
<td>Fax Number:</td>
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<td>* E-Mail:</td>
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<td>Credential, e.g., agency login:</td>
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<td>* Project Role:</td>
<td>PD/PI</td>
<td>Other Project Role Category:</td>
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<td>Degree Type:</td>
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<tr>
<td>Degree Year:</td>
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</table>

*Attach Biographical Sketch

Attach Current & Pending Support

**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).

### PROFILE - Senior/Key Person 1

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<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
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<td>* Last Name:</td>
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<td>Street2:</td>
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<td>* City:</td>
<td>County/ Parish:</td>
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<td>* State:</td>
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<tr>
<td>Country:</td>
<td>USA: UNITED STATES</td>
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<td>* Phone Number:</td>
<td>Fax Number:</td>
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<td>* E-Mail:</td>
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<td>Credential, e.g., agency login:</td>
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<td>* Project Role:</td>
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<td>Degree Year:</td>
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</tbody>
</table>

*Attach Biographical Sketch

Attach Current & Pending Support

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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: December 21, 2017
**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)  

- [ ] 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

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:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</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></td>
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<tr>
<td>1b. Anticipated Number of personnel to be employed at your organization at the time of award.</td>
<td></td>
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<tr>
<td>1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms?</td>
<td></td>
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<tr>
<td>1d. Is your small business a Faculty or Student-Owned entity?</td>
<td></td>
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<tr>
<td>2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?</td>
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<tr>
<td>* If yes, insert the names of the Federal laboratories/agencies:</td>
<td></td>
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<tr>
<td>* If yes, list the names of the other Federal agencies:</td>
<td></td>
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<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></td>
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<tr>
<td>4. Will all research and development on the project be performed in its entirety in the United States?</td>
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<td>* If no, provide an explanation in an attached file.</td>
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<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>
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<tr>
<td>* If yes, insert the names of the other Federal agencies:</td>
<td></td>
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<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></td>
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</tr>
<tr>
<td>7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase III Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.</td>
<td></td>
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</tr>
</tbody>
</table>

* 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-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>
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</table>

* Attach File: [Add Attachment] [Delete Attachment] [View Attachment]

* 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.

* 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.**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</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?

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

* 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?

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

If No to Human Subjects

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.

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

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

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

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

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.
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.

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

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

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 [Dropdown] Months  
- Maximum Age: [Dropdown] Years [Dropdown] Months

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: [Dropdown] MM/DD/YYYY

**Inclusion Enrollment Report(s)**

- [Dropdown]: Anticipated, Actual  
- Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

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>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not Hispanic or Latino</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hispanic or Latino</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td>Asian</td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td>White</td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td>More than One Race</td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>Female 0</td>
<td>Male 0</td>
</tr>
<tr>
<td>Racial Categories</td>
<td>Not Hispanic or Latino</td>
<td>Hispanic or Latino</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>American Indian/ Alaska Native</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>More than One Race</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

Delete Attachment  View Attachment

Add 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

Add Attachment  Delete Attachment  View Attachment

If yes, describe the single IRB plan

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

Delete Attachment  View Attachment

3.3. Data and Safety Monitoring Plan

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

Delete Attachment  View Attachment

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

☐ Yes  ☐ No

Delete Attachment  View Attachment

3.5. Overall Structure of the Study Team

Optional.

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

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>

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)

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.

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
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.
Optional form in most grant application packages.

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:  

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](https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents)

<table>
<thead>
<tr>
<th>Assign to Awarding Component:</th>
<th>First Choice</th>
<th>Second Choice</th>
<th>Third Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Assign to Awarding Component:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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](https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection)

<table>
<thead>
<tr>
<th>Assign to Study Section: Only 20 characters allowed</th>
<th>First Choice</th>
<th>Second Choice</th>
<th>Third Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Assign to Study Section: Only 20 characters allowed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
### 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 ($)**
**Funds Requested ($)**

**Project Role:**
- **PD/PI**

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

**Additional Senior Key Persons:**

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

**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.

### 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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</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)**

**Updated:** December 21, 2017
### 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>
</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

<table>
<thead>
<tr>
<th>Total Equipment</th>
</tr>
</thead>
</table>

### D. Travel

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

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

2. Foreign Travel Costs

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

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

Total Travel Cost

<table>
<thead>
<tr>
<th>Total Travel Cost</th>
</tr>
</thead>
</table>

### E. Participant/Trainee Support Costs

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

1. Tuition/Fees/Health Insurance

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

2. Stipends

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

3. Travel

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

4. Subsistence

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

5. Other

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

Number of Participants/Trainees  

<table>
<thead>
<tr>
<th>Total Participant/Trainee Support Costs</th>
</tr>
</thead>
</table>

Updated: December 21, 2017

FORMS-E Series  
Page 20 of 24
### 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. 
9. 
10. 

<table>
<thead>
<tr>
<th>Other Direct Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
</tbody>
</table>

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

### G. Direct Costs

<table>
<thead>
<tr>
<th>Direct Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G. Direct Costs</td>
<td></td>
</tr>
</tbody>
</table>

**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>
</table>

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

**Total Indirect Costs**

### I. Total Direct and Indirect Costs

<table>
<thead>
<tr>
<th>Total Direct and Indirect Institutional Costs (G + H)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
</table>

### J. Fee

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

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

### K. Total Costs and Fee

<table>
<thead>
<tr>
<th>Total Costs and Fee (I + J)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
</table>

### L. Budget Justification

<table>
<thead>
<tr>
<th>Budget Justification</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
</table>

Budget Justification is required and must cover all budget periods.
<table>
<thead>
<tr>
<th>Section A, Senior/Key Person</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Section B, Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
<td></td>
</tr>
<tr>
<td>Section C, Equipment</td>
<td></td>
</tr>
<tr>
<td>Section D, Travel</td>
<td></td>
</tr>
<tr>
<td>1. Domestic</td>
<td></td>
</tr>
<tr>
<td>2. Foreign</td>
<td></td>
</tr>
<tr>
<td>Section E, Participant/Trainee Support Costs</td>
<td></td>
</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td></td>
</tr>
<tr>
<td>2. Stipends</td>
<td></td>
</tr>
<tr>
<td>3. Travel</td>
<td></td>
</tr>
<tr>
<td>4. Subsistence</td>
<td></td>
</tr>
<tr>
<td>5. Other</td>
<td></td>
</tr>
<tr>
<td>6. Number of Participants/Trainees</td>
<td></td>
</tr>
<tr>
<td>Section F, Other Direct Costs</td>
<td></td>
</tr>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Other 1</td>
<td></td>
</tr>
<tr>
<td>9. Other 2</td>
<td></td>
</tr>
<tr>
<td>10. Other 3</td>
<td></td>
</tr>
<tr>
<td>Section G, Direct Costs (A thru F)</td>
<td></td>
</tr>
<tr>
<td>Section H, Indirect Costs</td>
<td></td>
</tr>
<tr>
<td>Section I, Total Direct and Indirect Costs (G + H)</td>
<td></td>
</tr>
<tr>
<td>Section J, Fee</td>
<td></td>
</tr>
<tr>
<td>Section K, Total Costs and Fee (I + J)</td>
<td></td>
</tr>
</tbody>
</table>

**Totals ($)**

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

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.