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

FORMS-F Series – Application due dates on/after May 25, 2020

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</tbody>
</table>

NOTES:

- The Funding Opportunity Announcement (FOA) and the SBIR/STTR Application Guide instructions are the official documents for defining application requirements. This resource is meant to complement, not replace, those documents.
  - Don’t forget to periodically check the Related Notices section of the FOA for updates to instructions or policies since the opportunity was posted.

- The blue annotations throughout this resource represent tips for completing form fields and avoiding common errors/warnings.

- Each funding opportunity has its own unique set of forms. Once you have identified an opportunity of interest, you must use a submission system (e.g., ASSIST) to access and prepare the forms.
  - Preparing Your Application Using ASSIST

- 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.

- Registration in multiple systems is needed prior to submission, see Get Registered! Can take 6 weeks – start early!
APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

1. TYPE OF SUBMISSION

Pre-application
Application
Changed/Corrected Application

2. DATE SUBMITTED

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

3. DATE RECEIVED BY STATE

Use Application for first submission attempt for due date.

4. a. Federal Identifier

State Application Identifier

4. b. Agency Routing Identifier

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

4. c. Previous Grants.gov Tracking ID

For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XX).

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

5. APPLICANT INFORMATION

Legal Name: Small business

Department: Division:

Street1: Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES

ZIP / Postal Code: 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: 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):

Small business must be in the U.S. or U.S. territory.

7. TYPE OF APPLICANT:

Please select one of the following

Other (Specify):

Small Business Organization Type

Women Owned

Socially and Economically Disadvantaged

Do not use these Small Business Organization Type checkboxes. NIH/CD/CD use SAM data to gather this information.

8. TYPE OF APPLICATION:

See application guide for definitions.

New

Resubmission

Renewal

Continuation

Revision

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.

The funding opportunity provides an "Earliest Project Start Date". For example, the omnibus/parent and other opportunities that use the Sept 5/Jan 5/April 5 standard due dates have corresponding Earliest Project Start Dates of April/July/September.

Generally, project durations are .. Phase 1: 6-12 months, Fast-Track: 2.5-3 yrs, Phase II: 2 yrs, Phase IIIB: up to 3 yrs, Commercialization Readiness Pilot (CRP): up to 3 years.
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: ___________________________ First Name: ___________________________ Middle Name: ___________________________
Last Name: ___________________________ 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.
Suffix: ___________________________
Position/Title: ___________________________
Organization Name: ___________________________
Department: ___________________________ Division: ___________________________
Street1: ___________________________
Street2: ___________________________
City: ___________________________ County / Parish: ___________________________
State: ___________________________ Province: ___________________________
Country: USA: UNITED STATES ___________________________ ZIP / Postal Code: ___________________________
Phone Number: ___________________________ Fax Number: ___________________________
Email: ___________________________

15. ESTIMATED PROJECT FUNDING
Manually enter amounts.
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?
☐ YES ☐ NO
☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW
☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR
☐ 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. 18," if applicable.

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

20. Pre-application
☐ YES ☐ NO

21. Cover Letter Attachment
Cover letter is posted separately in eRA Commons, is not part of the assembled application image, and content is only available to select agency staff. If Phase 1 or Phase II was a contract or awarded from another agency, include contract/award number. If application proposes the use of human fetal tissue (HFT) from elective abortions, you must include a Cover Letter with a statement about HFT involvement.

*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  

**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  

**Answer required if euthanasia is NOT consistent with AVMA guidelines. Up to 1000 characters.**

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.

<table>
<thead>
<tr>
<th><em>Budget Period</em></th>
<th><em>Anticipated Amount ($)</em></th>
<th><em>Source(s)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Up to 150 characters.</td>
<td></td>
</tr>
</tbody>
</table>

Form accommodates up to 10 budget periods. 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. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions?*  
- [ ] Yes  
- [ ] No

If "yes" then provide the HFT Compliance Assurance

**Required if Yes. Cannot be included if No.**

If "yes" then provide the HFT Sample IRB Consent Form

**Required if Yes. Cannot be included if No.**
## 5. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents:  Yes [ ] No [ ]

If "Yes" then answer the following:

*Previously Reported:  Yes [ ] No [ ]

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## 6. Change of Investigator/Change of Institution Section

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

- **Change of Project Director/Principal Investigator**
  - Name of former Project Director/Principal Investigator:
    - Prefix:
    - *First Name:*
    - Middle Name:
    - *Last Name: If change of PD/PI box is checked, you must provide the last name of the former PD/PI.*
    - Suffix:

- **Change of Grantee Institution**
  - *Name of former institution: If change of Grantee Institution box is checked, you must provide the 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. 1 2 3 4 5 6 7 8
      IRB Approval Date: ________
      Human Subject Assurance Number: ________

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: ________

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

6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No
   a. If yes, identify countries: If 6a is Yes, then a list of countries is required in 6a. Abbreviations can be used. 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. Research must be performed in U.S. facilities. Foreign sites must be approved by the funding officer.

11. Equipment
    Required unless otherwise noted in opportunity. Limited system enforcement.

12. Other Attachments
    Only provide Other Attachments when requested in the funding opportunity announcement, notice of special interest or application guide. If provided, follow any guidance regarding attachment filenames.
    Field accommodates multiple attachments.
### Project/Performance Site Location(s)

**Primary Location**

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

**Additional Location(s)**

- **Street1:**
- **City:**
- **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**

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**NIH Office of Extramural Research**

**FORMS-F Series (Updated February 18, 2021)**

**Page 7**
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
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</thead>
<tbody>
<tr>
<td>* Last Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
<td></td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Division:</td>
<td></td>
</tr>
<tr>
<td>* Street1: 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>
<td></td>
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<td>Street2:</td>
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<td>* E-Mail:</td>
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<tr>
<td>Credential, e.g., agency login:</td>
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<tr>
<td>* Project Role: PD/PI</td>
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<tr>
<td>Other Project Role Category:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree Type:</td>
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<tr>
<td>Degree Year:</td>
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</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Last Name:</td>
<td></td>
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<tr>
<td>Position/Title:</td>
<td>Department:</td>
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<tr>
<td>Organization Name:</td>
<td>Division:</td>
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</tr>
<tr>
<td>* Street1: 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>Street2:</td>
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<td>* City:</td>
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<td></td>
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<tr>
<td>* State:</td>
<td></td>
<td></td>
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<tr>
<td>* Country: USA: UNITED STATES</td>
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<td>* Zip / Postal Code:</td>
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<td>Credential, e.g., agency login:</td>
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<tr>
<td>* Project Role:</td>
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<tr>
<td>Other Project Role Category:</td>
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<tr>
<td>Degree Type:</td>
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<tr>
<td>Degree Year:</td>
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</tbody>
</table>

**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.**

#### Biographical Sketch

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

#### Current & Pending Support

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

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<table>
<thead>
<tr>
<th>Delete Entry</th>
<th>Next Person</th>
</tr>
</thead>
</table>

 NIH Office of Extramural Research  
 FORMS-F Series (Updated February 18, 2021)  
 Page 8
### RESEARCH & RELATED BUDGET - Budget Period 1

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

**ORGANIZATIONAL DUNS:**

**Enter name of Organization:**

**Budget Period:**
- Start Date: 
- End Date: 

**Project Subaward/Consortium**

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

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

**A. Senior/Key Person**

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

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

**Project Role:** PD/PI

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

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

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>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)**
### 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>
<td></td>
<td></td>
</tr>
</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:**

- Total funds requested for all equipment listed in the attached file
- Total Equipment

### D. Travel

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

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

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

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant/Trainee Support Costs</th>
</tr>
</thead>
</table>
### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Item</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>
<tr>
<td>8. If requesting Technical and Business Assistance (TABA) funding, you must include a &quot;Technical Assistance&quot; line item in line 8, 9, or 10. See NOT-OD-21-062.</td>
<td></td>
</tr>
<tr>
<td>9. If proposing the use of human fetal tissue from elective abortions, you must include a &quot;Human Fetal Tissue Costs&quot; line item in line 8, 9 or 10.</td>
<td></td>
</tr>
</tbody>
</table>

Total Other Direct Costs

### G. Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct Costs (A thru F)</td>
<td></td>
</tr>
</tbody>
</table>

### 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

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

### I. Total Direct and Indirect Costs

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

### J. Fee

A reasonable fee, not to exceed 7% of total costs for each Phase of the project is available with SBIR/STTR awards. A Fee cannot be entered for a Subaward/Consortium budget.

### K. Total Costs and Fee

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

### L. Budget Justification

Budget Justification is required and must cover all budget periods.
**RESEARCH & RELATED BUDGET - Cumulative Budget**

**Section A, Senior/Key Person**

<table>
<thead>
<tr>
<th>Totals ($)</th>
</tr>
</thead>
</table>

**Section B, Other Personnel**

<table>
<thead>
<tr>
<th>Total Number Other Personnel</th>
</tr>
</thead>
</table>

**Section C, Equipment**

<table>
<thead>
<tr>
<th>Total Salary, Wages and Fringe Benefits (A+B)</th>
</tr>
</thead>
</table>

**Section D, Travel**

<table>
<thead>
<tr>
<th>1. Domestic</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Foreign</td>
</tr>
</tbody>
</table>

**Section E, Participant/Trainee Support Costs**

<table>
<thead>
<tr>
<th>1. Tuition/Fees/Health Insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Stipends</td>
</tr>
<tr>
<td>3. Travel</td>
</tr>
<tr>
<td>4. Subsistence</td>
</tr>
<tr>
<td>5. Other</td>
</tr>
<tr>
<td>6. Number of Participants/Trainees</td>
</tr>
</tbody>
</table>

**Section F, Other Direct Costs**

<table>
<thead>
<tr>
<th>1. Materials and Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Publication Costs</td>
</tr>
<tr>
<td>3. Consultant Services</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
</tr>
<tr>
<td>8. Other 1</td>
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<td>9. Other 2</td>
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<tr>
<td>10. Other 3</td>
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**Section G, Direct Costs (A thru F)**

<table>
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<tr>
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**Section H, Indirect Costs**

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<th>Totals ($)</th>
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**Section I, Total Direct and Indirect Costs (G + H)**

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<tr>
<th>Totals ($)</th>
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**Section J, Fee**

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<th>Totals ($)</th>
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</table>

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

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<th>Totals ($)</th>
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</table>

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.

<table>
<thead>
<tr>
<th>Attachment</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
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<tbody>
<tr>
<td>1) Please attach Attachment 1</td>
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<td>30) Please attach Attachment 30</td>
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</tbody>
</table>
# PHS 398 Research Plan

## Introduction

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

## 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.
   - Add Attachment  |  Delete Attachment  |  View 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.**

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.**

8. **Consortium/Contractual Arrangements**
   - Add Attachment  |  Delete Attachment  |  View Attachment

9. **Letters of Support**
   - 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

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

* 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.

* 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? Selection required.

* 1d. Is your small business a Faculty or Student-Owned entity? Selection required.

* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? *Selection required.

* If yes, insert the names of the Federal laboratories/agencies:

Required if Yes. Up to 250 characters. Cannot include if 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.

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

Explanation: Required if No. Cannot include if Yes.

* 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? *Selection required.

* If yes, insert the names of the other Federal agencies:

Required if Yes. Up to 250 characters. Cannot include if 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 III Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. *Attachment.

Required for Phase II, Direct Phase II, Phase IIB, Phase I/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.

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

* 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]

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

* 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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<tbody>
<tr>
<td>☐</td>
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</tbody>
</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>
</tr>
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<tbody>
<tr>
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</tbody>
</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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<tbody>
<tr>
<td>☐</td>
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</tbody>
</table>

* 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.]
Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data?  
[ ] Yes  [ ] No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Only include attachment if proposed research uses human specimens and/or data not considered to be human subjects research.

If No to Human Subjects

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 a study name and justification for omission of human subject study information.

Other Requested Information

Only provide an Other Requested Information attachment when specifically 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

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

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.

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.
### 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
- [x] No

If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

1.3. Exemption Number

- [ ] 1
- [ ] 2
- [ ] 3
- [ ] 4
- [ ] 5
- [ ] 6
- [ ] 7
- [ ] 8

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

1.4. *Clinical Trial Questionnaire*

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
- [x] No

1.4.b. Are the participants prospectively assigned to an intervention?
- [ ] Yes
- [x] No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?
- [ ] Yes
- [x] No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
- [ ] Yes
- [x] No

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

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.

### Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

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

2.2. Eligibility Criteria

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

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

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

2.3. Age Limits

Minimum Age

Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan

Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

2.4. Inclusion of Women and Minorities

Inclusion of Women and Minorities as Participants in Research Involving Human Subjects

2.5. Recruitment and Retention Plan

Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

2.6. Recruitment Status

Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

2.7. Study Timeline

Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in opportunity.

2.8. Enrollment of First Participant

Date: MM/DD/YYYY

Dropdown list: Anticipated, Actual

Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset.

2.9. Inclusion Enrollment Report(s)

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

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.
## Inclusion Enrollment Report

1. **Inclusion Enrollment Report Title**
   - Required. Up to 600 characters.

2. **Using an Existing Dataset or Resource**
   - Yes
   - No
   - Answer required and system enforced.

3. **Enrollment Location Type**
   - Domestic
   - Foreign
   - Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

4. **Enrollment Country(ies)**
   - Multi-select from list of countries.

5. **Enrollment Location(s)**

6. **Comments**
   - Up to 500 characters.
<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th></th>
<th></th>
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</tr>
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<td></td>
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Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

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 if study is not exempt from federal regulations (i.e., Question 1.2 is No).

If yes, describe the single IRB plan

NIH: If Yes, not required.
AHRQ: If Yes, required.

3.3. Data and Safety Monitoring Plan

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

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.

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. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose

Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other

4.1.c. Interventions

Up to 20 Interventions allowed.

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
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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)

4.1.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 N/A

Is this an NIH-defined Phase III clinical trial?

□ Yes  □ No

4.1.e. Intervention Model

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

4.1.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.

4.1.g. Allocation

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

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<th>Name</th>
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<td>Type</td>
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<td>Time Frame</td>
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<td>Brief Description</td>
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4.3. Statistical Design and Power

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

4.4. Subject Participation Duration

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

4.5. Will the study use an FDA-regulated intervention?

Yes  No

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

4.5.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.

4.6. Is this an applicable clinical trial under FDAAA?

Yes  No

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

Funding Opportunity Number:

Pre-populated from announcement information.

Funding Opportunity Title:

Awarding Component Assignment Suggestions (optional)

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components:

Study Section Assignment Suggestions (optional)

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for "Suggested Study Sections." Remove all hyphens, parentheses, and spaces. All suggestions will be considered; however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections:

Rationale for assignment suggestions (optional)

Entry is limited to 1000 characters.

Up to 1000 characters.
List individuals who should not review your application and why (optional)

Provide sufficient information (e.g., name, organization, affiliation) to correctly identify each individual. Provide specific reason why an individual should not review your application. Information will be considered, but listing an individual does not guarantee they will not be on review panel.

Identify scientific areas of expertise needed to review your application (optional)

Note: Do not provide names of individuals

Expertise:
Each entry is limited to 40 characters

Limit your answers to expertise. DO NOT enter the names of individuals you'd like to review your application.