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

FORMS-G Series – Application due dates on/after January 25, 2022

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NOTES:

- The Funding Opportunity Announcement (FOA) and the [SBIR/STTR Application Guide instructions](#) are the official documents for application requirements. This resource is meant to complement, not replace, those documents.
  - Periodically check the Related Notices section of the FOA for updates to instructions or policies since the opportunity was posted.
- Blue annotations in this resource represent tips for completing form fields and avoiding common errors/warnings.
- Each [SBIR and STTR 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 required – see [Register Your Company](#)! Can take 6 weeks – start early!
- Learn [How to Apply](#) for NIH small business funding on the [NIH SEED website](#).
**APPLICATION FOR FEDERAL ASSISTANCE**

**SF 424 (R&R)**

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

**2. DATE SUBMITTED**
- Applicant Identifier

**5. APPLICANT INFORMATION**
- Legal Name:
- Department:
- Division:
- Street1:
- Street2:
- City:
- State:
- ZIP / Postal Code:
- Country:
- Prefix:
- First Name:
- Middle Name:
- Last Name:
- Suffix:
- Position/Title:
- Street1:
- Street2:
- City:
- County / Parish:
- Province:
- State:
- ZIP / Postal Code:
- Country:
- 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 U.S. or U.S. territory.

**7. TYPE OF APPLICANT:**
- Please select one of the following:
- Other (Specify):
- Women Owned
- Socially and Economically Disadvantaged
- Do not use these Small Business Organization Type checkboxes. NIH/CDC/FDA use SAM data to gather this information.

**8. TYPE OF APPLICATION:**
- New
- Resubmission
- Renewal
- Continuation
- Revision
- See application guide for definitions.
- If Revision, mark appropriate box(es):
  - A. Increase Award
  - B. Decrease Award
  - C. Increase Duration
  - D. Decrease Duration
  - E. Other (specify):

**9. NAME OF FEDERAL AGENCY:**

**10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:**
- CFDA is also referred to as Assistance Listing Number (ALN).
- NIH will assign CFDA/ALN 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:
- 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/Jun 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 IIB: up to 3 yrs, Commercialization Readiness Pilot (CRP): up to 3 years.
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: ___________________________ First 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 FORMS-G: Updated country list. ZIP / Postal Code: ___________________________
Phone Number: ___________________________ Fax Number: ___________________________
Email: ___________________________

15. ESTIMATED PROJECT FUNDING
Manually enter estimated project funding 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?

a. YES ___________________________
   THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
   DATE: ___________________________
SBIR/STTR: Check "No - Program is not covered by E.O. 12372: OR
b. NO ___________________________
   PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

I agree ___________________________

See the NIH Grants Policy Statement section 4.1 Public Policy Requirements and Objectives for more information.

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

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation
Add Attachment Delete Attachment View Attachment

19. Authorized Representative
Prefix: ___________________________ First Name: ___________________________
Last Name: ___________________________ Suffix: ___________________________
Position/Title: ___________________________
Organization Name: ___________________________
Department: ___________________________ Division: ___________________________
Street1: ___________________________
Street2: ___________________________
City: ___________________________ County / Parish: ___________________________
State: ___________________________ Province: ___________________________
Country: USA: UNITED STATES FORMS-G: Updated country list. ZIP / Postal Code: ___________________________
Phone Number: ___________________________ Fax Number: ___________________________
Email: ___________________________

Authorized Organization Representative (AOR) in Grants.gov must have signature authority for the organization. The electronic signature of the submitting AOR is recorded with submission.
In eRA Commons individuals with signature authority are called Signing Officials (SOs).

Signature of Authorized Representative ___________________________
Date Signed ___________________________

20. Pre-application
Cover letter is posted as a separate document in eRA Commons and is not part of the assembled application image. Content is only made available to select agency staff. 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.

21. Cover Letter Attachment
Add Attachment Delete Attachment View Attachment
1. Vertebrate Animals Section

Are vertebrate animals euthanized?  

☐ Yes  ☐ No  

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

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines?  

☐ Yes  ☐ No  

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

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

2. Program Income Section

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

☐ Yes  ☐ No

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

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

Up to 150 characters.

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

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

Error if provided human fetal tissue obtained from elective abortions is 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.
5. Inventions and Patents Section (for Renewal applications)  

*Inventions and Patents:  Yes [  ]  No [  ]

If "Yes" then answer the following:

*Previously Reported:  Yes [  ]  No [  ]

| SBIR/STTR: Only applies to Phase II applications. |

6. 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:  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. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? □ Yes □ No
   4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment?
   4.b. If yes, please explain: If 4a is Yes, then 4b is required. Up to 55 characters.
   4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? □ Yes □ No
      If yes, please explain: If 4c is Yes, then 4d is required. Up to 55 characters.

5. Is the research performance site designated, or eligible to be designated, as a historic place? □ Yes □ No
   5.a. If yes, please explain: If 5 is Yes, then 5a is required. Up to 55 characters.

6. Does this project involve activities outside of the United States or partnerships with international collaborators? □ Yes □ No
   6.a. If yes, identify countries: If 6 is Yes, then a list of countries is required in 6a. Abbreviations can be used. 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)

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

Organization Name: 

UEI: 

Street1: 

City: 

* State: 

Province: 

* Country: USA: UNITED STATES 

* ZIP / Postal Code: 

* Project/ Performance Site Congressional District: 

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

### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix:</td>
<td>* First Name:</td>
</tr>
<tr>
<td>* Last Name:</td>
<td>Middle Name:</td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Division:</td>
</tr>
<tr>
<td>* Street1:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
</tr>
<tr>
<td>* City:</td>
<td>County/ Parish:</td>
</tr>
<tr>
<td>* State:</td>
<td>Province:</td>
</tr>
<tr>
<td>Country:</td>
<td>USA: UNITED STATES</td>
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<tr>
<td>* Zip / Postal Code:*</td>
<td>* Country:</td>
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<tr>
<td>* State:</td>
<td></td>
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<tr>
<td>* City:</td>
<td></td>
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<tr>
<td>* Phone Number:</td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td></td>
</tr>
</tbody>
</table>

### PROFILE - Senior/Key Person 1

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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<tbody>
<tr>
<td>Prefix:</td>
<td>* First Name:</td>
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<tr>
<td>* Last Name:</td>
<td>Middle Name:</td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Division:</td>
</tr>
<tr>
<td>* Street1:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
</tr>
<tr>
<td>* City:</td>
<td>County/ Parish:</td>
</tr>
<tr>
<td>* State:</td>
<td>Province:</td>
</tr>
<tr>
<td>Country:</td>
<td>USA: UNITED STATES</td>
</tr>
<tr>
<td>* Zip / Postal Code:*</td>
<td>* Country:</td>
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<tr>
<td>* State:</td>
<td></td>
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<tr>
<td>* City:</td>
<td></td>
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<tr>
<td>* Phone Number:</td>
<td></td>
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<tr>
<td>* E-Mail:</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
- OMB Number: 4040-0001
- Expiration Date: 12/31/2022
- 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.
RESEARCH & RELATED BUDGET - Budget Period 1

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

**UEI:**
- [ ] Project
- [ ] Subaward/Consortium

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

**Start Date:** — **End Date:**

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 ($)** | **Months** | **Cal. Acad. Sum.** | **Requested Salary ($)** | **Fringe Benefits ($)** | **Funds Requested ($)**
--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | ---

**Project Role:**
- PD/PI

**Additional Senior Key Persons:**

If more than 8 Sr/Key (100 for multi-project applications), 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><strong>Cal.</strong></th>
<th><strong>Acad.</strong></th>
<th><strong>Sum.</strong></th>
<th><strong>Requested Salary ($)</strong></th>
<th><strong>Fringe Benefits ($)</strong></th>
<th><strong>Funds Requested ($)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
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<tr>
<td></td>
<td>Graduate Students</td>
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<tr>
<td></td>
<td>Undergraduate Students</td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
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<tr>
<td></td>
<td>Total Number Other Personnel</td>
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</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 Other Personnel**

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

NIH Office of Extramural Research

FORMS-G Series (Updated Feb. 7, 2022)
### 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>Enter up to 10 equipment items.</td>
<td></td>
</tr>
</tbody>
</table>

If more than 10 Equipment items (100 for multi-project applications), use attachment and enter total funds requested for additional equipment.

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

1. Tuition/Fees/Health Insurance

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

2. Stipends

3. Travel

4. Subsistence

5. Other

Number of Participants/Trainees

Total Participant/Trainee Support Costs
### 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

---

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

---

### G. Direct Costs

Total Direct Costs (A thru F)

### H. Indirect Costs

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

Total Direct and Indirect Institutional Costs (G + H)

### 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

Total Costs and Fee (I + J)

---

### L. Budget Justification

(Only attach one file.)

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

**Totals ($)**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Senior/Key Person</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Other Personnel</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Equipment</td>
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</tr>
<tr>
<td>D</td>
<td>Travel</td>
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<td>Domestic</td>
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<tr>
<td>D2</td>
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<td>E3</td>
<td>Subsistence</td>
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<td>E4</td>
<td>Other</td>
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<td>Number of Participants/Trainees</td>
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<td>F</td>
<td>Other Direct Costs</td>
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<tr>
<td>F1</td>
<td>Materials and Supplies</td>
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<td>F2</td>
<td>Publication Costs</td>
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<td>F3</td>
<td>Consultant Services</td>
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<td>ADP/Computer Services</td>
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<td>F5</td>
<td>Subawards/Consortium/Contractual Costs</td>
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<td>F6</td>
<td>Equipment or Facility Rental/User Fees</td>
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<td>F7</td>
<td>Alterations and Renovations</td>
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<tr>
<td>F8</td>
<td>Other 1</td>
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<td>F10</td>
<td>Other 3</td>
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</tr>
<tr>
<td>F11</td>
<td>Other 4: Increased number of additional Other Direct Costs line items from 3 to 10.</td>
<td></td>
</tr>
<tr>
<td>F12</td>
<td>Other 5</td>
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<td>F13</td>
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<tr>
<td>F14</td>
<td>Other 7</td>
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</tr>
<tr>
<td>F15</td>
<td>Other 8</td>
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<tr>
<td>F16</td>
<td>Other 9</td>
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<tr>
<td>F17</td>
<td>Other 10</td>
<td></td>
</tr>
</tbody>
</table>
Section G, Direct Costs (A thru F)
Section H, Indirect Costs
Section I, Total Direct and Indirect Costs (G + H)
Section J, Fee
Section K, Total Costs and Fee (I + J)
**R&R SUBAWARD BUDGET ATTACHMENT(S) FORM**

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

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

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

### Other Research Plan Section
5. Vertebrate Animals  
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
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

**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.
SBIR/STTR Information

OMB Number: 4040-0001
Expiration Date: 12/31/2022

* 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.

The 9-digit code is included in the registry filename received from SBA upon registration (e.g., SBC_123456789.pdf.)

* 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
- [ ] Phase IIC
- [ ] Commercialization Readiness Program (See agency-specific instructions to determine application type participation.)

Phase I Letter of Intent Number: Leave blank. N/A for HHS (NIH, CDC, FDA) submissions. Workspace users: Enter 0.

* Agency Topic/Subtopic: [ ] Optional.

Questions 1-8 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? [ ] Yes [ ] No

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? [ ] Yes [ ] No

Selection required.

* 1d. Is your small business a Faculty or Student-Owned entity? [ ] Yes [ ] No

* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? [ ] Yes [ ] No

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 [ ] Yes [ ] No

Selection required.

* 4. Will all research and development on the project be performed in its entirety in the United States? [ ] Yes [ ] No

If no, provide an explanation in an attached file.

* 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? [ ] Yes [ ] No

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)? [ ] Yes [ ] No

Selection required.

* 7. Does the application include a request of SBIR or STTR funds for Technical and Business Assistance (TABA)? If yes, please follow the agency specific instructions to provide the budget request and justification. (Please answer no if you plan to use the agency TABA vendor, which does not require you to include a request for TABA funds in your application.) [ ] Yes [ ] No

* 8. 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.

* Attach File: [ ] Required for Phase II, Direct Phase II, Phase IIIB, 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 9 and 10 apply only to SBIR applications. If you are submitting **ONLY** an STTR application, leave questions 9 and 10 blank and proceed to question 11.**

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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#### STTR-Specific Questions:
*Answers only required for STTR applications.*

*Questions 11 - 13 apply only to STTR applications. If you are submitting **ONLY** an SBIR application, leave questions 11 - 13 blank.*

<table>
<thead>
<tr>
<th>Yes</th>
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* 11. 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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<th>Yes</th>
<th>No</th>
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* 12. 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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<th>Yes</th>
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* 13. Provide UEI of non-profit research partner for STTR.

FORMS-G: Enter the Unique Entity Identifier (UEI) 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.

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

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

If Yes to Human Subjects

Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).

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.

Click here to extract the Human Subject Study Record Attachment

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.

Delayed Onset Study(ies)

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.

Study Title | Anticipated Clinical Trial? | Justification
--- | --- | ---

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

* Always required field

Section 1 - Basic Information

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

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

1.2. * Is this Study Exempt from Federal Regulations?

Yes ☐  No ☐

Answer required and system enforced.

1.3. Exemption Number

☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5  ☐ 6  ☐ 7  ☐ 8

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

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 ☐

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

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

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.

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)

2.3. Age Limits

Minimum Age

Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan

Required and system enforced unless exemption 4 is only exemption selected.

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

2.4. Inclusion of Women and Minorities

Required and system enforced unless exemption 4 is only exemption selected.

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.

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.
PHS 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.
   FORMS-G: Updated country selection list.

5. Enrollment Location(s)

6. 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>
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</thead>
<tbody>
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### Ethnic Categories

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</thead>
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<td>Male</td>
<td>Unknown/Not Reported</td>
<td>Female</td>
</tr>
<tr>
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<tr>
<td>Asian</td>
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<td>Black or African American</td>
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</table>

Report 1 of 1
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).

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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Up to 200 characters.</td>
<td>Up to 1,000 characters.</td>
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</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)

4.1.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

<table>
<thead>
<tr>
<th>Name</th>
<th>Up to 255 characters.</th>
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<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>

### 4.3. 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: _____________________________  _____________________________  _____________________________

Suggestions are considered with other assignment factors. Not all suggestions can be honored.

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: _____________________________  _____________________________  _____________________________

Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Rationale for assignment suggestions (optional)  

Entry is limited to 1000 characters.

Up to 1000 characters.
# PHS Assignment Request Form

**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*

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<th>Expertise</th>
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<th>2</th>
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Limit your answers to expertise. DO NOT enter the names of individuals you'd like to review your application.