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</tbody>
</table>

NOTES:

- The funding opportunity 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 funding opportunity 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

3. DATE RECEIVED BY STATE

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

4. b. Agency Routing Identifier

4. c. Previous Grants.gov Tracking ID
   - For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX).
   - If Changed/Corrected (box 1), provide previous Grants.gov tracking # (e.g., GRANT12345678).

5. APPLICANT INFORMATION
- Applicant Identifier

6. EMPLOYER IDENTIFICATION (EIN) or (TIN):
- Must provide zip+4 for all zip codes.

7. TYPE OF APPLICANT:
- Other (Specify):
- Small business must be in U.S. or U.S. territory.

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

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

13. CONGRESSIONAL DISTRICT OF APPLICANT
- Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). Use 00-000 if outside the US.
- 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 I: 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

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>First Name:</th>
<th>Middle Name:</th>
<th>Last Name:</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>PD/PI first/last name should match name on file for Commons ID provided in the Credential field of the R&amp;R Senior/Key Person Profile (Expanded) form.</td>
<td></td>
</tr>
<tr>
<td>Position/Title:</td>
<td></td>
<td></td>
<td>Organization Name:</td>
<td></td>
</tr>
<tr>
<td>Department:</td>
<td></td>
<td></td>
<td>Street1:</td>
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<tr>
<td>Street2:</td>
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<td></td>
<td>City:</td>
<td>County / Parish:</td>
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<tr>
<td>State:</td>
<td></td>
<td></td>
<td>Country:</td>
<td>USA: UNITED STATES</td>
</tr>
<tr>
<td>ZIP / Postal Code:</td>
<td></td>
<td></td>
<td>Province:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Fax Number:</td>
<td>Email:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. ESTIMATED PROJECT FUNDING

<table>
<thead>
<tr>
<th>Manually enter estimated project funding amounts.</th>
<th>a. Total Federal Funds Requested</th>
<th>b. Total Non-Federal Funds</th>
<th>c. Total Federal &amp; Non-Federal Funds</th>
<th>d. Estimated Program Income</th>
</tr>
</thead>
</table>

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

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

*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

19. Authorized Representative

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>First Name:</th>
<th>Middle Name:</th>
<th>Last Name:</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position/Title:</td>
<td></td>
<td></td>
<td>Organization:</td>
<td></td>
</tr>
<tr>
<td>Department:</td>
<td></td>
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<td>Street1:</td>
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<td>Street2:</td>
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<td>City:</td>
<td>County / Parish:</td>
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<td>State:</td>
<td></td>
<td></td>
<td>Country:</td>
<td>USA: UNITED STATES</td>
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<tr>
<td>ZIP / Postal Code:</td>
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<td>Province:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Fax Number:</td>
<td>Email:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

View Attachment
Delete Attachment
Add 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  
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.

*Budget Period  *Anticipated Amount ($)  *Source(s)  
[Blank]  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:  
https://grants.nih.gov/stem_cells/registry/current.htm. 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):

[Blank]  
Error if provided human embryonic stem cell lines are not listed at https://grants.nih.gov/stem_cells/registry/current.htm 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 ☐

6. Change of Investigator/Change of Institution Section

☐ 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?  
      If yes, check appropriate exemption number.  
      If no, is the IRB review Pending?  
      If yes, IRB Approval Date:  
      Human Subject Assurance Number: 

2. Are Vertebrate Animals Used?  
   2.a. If YES to Vertebrate Animals 
      Is the IACUC review Pending?  
      IACUC Approval Date:  
      Animal Welfare Assurance Number: 

3. Is proprietary/privileged information included in the application? 

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? 
   4.d. If yes, please explain: If 4c is Yes, then 4d is required. Up to 55 characters. 

5. Is the research performance site designated, or eligible to be designated, as a historic place? 
   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? 
   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)

**Project/Performance Site Primary Location**

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

**Organization Name:**

**UEI:** Unique Entity Identifier (UEI) required and enforced by NIH.

* Street1:

* Street2:

* City:

* County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code:

* Project/Performance Site Congressional District:

---

**Project/Performance Site Location 1**

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

**Organization Name:**

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

* Street1:

* Street2:

* City:

County:

* 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/all-forms-and-formats/additional-performance-site-format.
RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Project Director/Principal Investigator**

Prefix:  
* First Name:  Middle Name:  Suffix:  
* Last Name:  
Position/Title:  
Department:  100 characters.  
Organization Name:  
Division:  100 characters.  
* 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.  
Street2:  
* City:  
County/ Parish:  
State:  
Province:  
* Country:  USA: UNITED STATES  
* Zip / Postal Code:  
* Phone Number:  
Fax Number:  
* E-Mail:  
Credential, e.g., agency login:  
* Project Role:  Other Project Role Category:  
Degree Type:  
Degree Year:  
*Attach Biographical Sketch  
Attach Current & Pending Support  

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

**PROFILE - Senior/Key Person 1**

Prefix:  
* First Name:  Middle Name:  Suffix:  
* Last Name:  
Position/Title:  
Department:  100 characters.  
Organization Name:  
Division:  100 characters.  
* 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.  
Street2:  
* City:  
County/ Parish:  
State:  
Province:  
* Country:  USA: UNITED STATES  
* Phone Number:  
Fax Number:  
* E-Mail:  
Credential, e.g., agency login:  
* Project Role:  Other Project Role Category:  
Degree Type:  
Degree Year:  
*Attach Biographical Sketch  
Attach Current & Pending Support  

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

NIH Office of Extramural Research  
FORMS-H Series (Updated March 28, 2023)
# RESEARCH & RELATED BUDGET - Budget Period 1

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

**Start Date:**

**End Date:**

**UEI:**

**Project Subaward/Consortium Budget Period:** 1

**OMB Number:** 4040-0001

**Expiration Date:** 11/30/2025

## 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 ($):**

  **Requested Salary ($):**

  **Fringe Benefits ($):**

  **Funds Requested ($):**

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

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

## 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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cal.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acad.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sum.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Graduate Students</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Number Other Personnel</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Other Personnel</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

**If more than 8 Sr/Key (100 for multi-project applications), use attachment and enter total funds requested for additional Sr/Key persons.**

**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.**

**FORMS-H:** If a Data Management and Sharing (DMS) plan is included, additional personnel costs specific to DMS activities must not be included in sections A. Senior/Key Person and B. Other Personnel. All DMS costs including personnel must be listed as a specific line item under Section F.8-17 Other.
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>

Additional Equipment:  

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

<table>
<thead>
<tr>
<th>Total funds requested for all equipment listed in the attached file</th>
<th>Total Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.*

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

E. Participant/Trainee Support Costs

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

1. Tuition/Fees/Health Insurance  
2. Stipends  
3. Travel  
4. Subsistence  
5. Other

<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>Line 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. Up to 10 additional Other Direct Costs line items can be added.</td>
<td></td>
</tr>
<tr>
<td>9. If requesting Technical and Business Assistance (TABA) funding,</td>
<td></td>
</tr>
<tr>
<td>10. See NOT-OD-21-062</td>
<td></td>
</tr>
<tr>
<td>11. FORMS-H: If a Data Management and Sharing (DMS) plan is included,</td>
<td></td>
</tr>
<tr>
<td>12. and Shading Costs line item covering DMS costs, including personnel</td>
<td></td>
</tr>
<tr>
<td>13. costs (e.g., personnel who will be curating data for the project).</td>
<td></td>
</tr>
<tr>
<td>14. If no cost incurred, enter 0. Type the string as requested</td>
<td></td>
</tr>
<tr>
<td>15. (without quotation marks) and do not combine the line item with any</td>
<td></td>
</tr>
<tr>
<td>16. “Other” costs.</td>
<td></td>
</tr>
<tr>
<td>17. If proposing the use of human fetal tissue from elective abortions,</td>
<td></td>
</tr>
<tr>
<td>18. you must include a “Human Fetal Tissue Costs” line item (if no</td>
<td></td>
</tr>
<tr>
<td>19. cost incurred, enter 0). Type the string as requested (without</td>
<td></td>
</tr>
<tr>
<td>20. quotation marks) and do not combine the line item with any “Other”</td>
<td></td>
</tr>
<tr>
<td>21. costs.</td>
<td></td>
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</tbody>
</table>

**Total Other Direct Costs**

### G. Direct Costs

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

<table>
<thead>
<tr>
<th>Total Indirect Costs</th>
</tr>
</thead>
</table>

**Cognizant Federal Agency**

(agency name, POC name, and POC phone number)

### I. Total Direct and Indirect Costs

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

### J. Fee

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

### K. Total Costs and Fee

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

### L. Budget Justification

(Only attach one file.)

**Add Attachment**

**Delete Attachment**

**View Attachment**

- **Budget Justification is required and must cover all budget periods.**
- **FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a section titled "Data Management and Sharing Justification" that provides a brief summary of DMS activities and justification for their costs.**
### RESEARCH & RELATED BUDGET - Cumulative Budget

<table>
<thead>
<tr>
<th>Section A, Senior/Key Person</th>
<th>Totals ($)</th>
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<tr>
<td>Section B, Other Personnel</td>
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<tr>
<td>Total Number Other Personnel</td>
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</table>

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

<table>
<thead>
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<th>Section D, Travel</th>
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<tbody>
<tr>
<td>1. Domestic</td>
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<tr>
<td>2. Foreign</td>
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</table>

### Section E, Participant/Trainee Support Costs

| 1. Tuition/Fees/Health Insurance |          |
| 2. Stipends                    |          |
| 3. Travel                      |          |
| 4. Subsistence                |          |
| 5. Other                      |          |
| 6. Number of Participants/Trainees |      |

### Section F, Other Direct Costs

<p>| 1. Materials and Supplies      |          |
| 2. Publication Costs           |          |
| 3. Consultant Services         |          |
| 4. ADP/Computer Services       |          |
| 5. Subawards/Consortium/Contractual Costs | |
| 6. Equipment or Facility Rental/User Fees | |
| 7. Alterations and Renovations |          |
| 8. Other 1                     |          |
| 9. Other 2                     |          |
| 10. Other 3                    |          |
| 11. Other 4                    |          |
| 12. Other 5                    |          |
| 13. Other 6                    |          |
| 14. Other 7                    |          |
| 15. Other 8                    |          |
| 16. Other 9                    |          |
| 17. Other 10                   |          |</p>
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<tr>
<td>H, Indirect Costs</td>
<td></td>
</tr>
<tr>
<td>I, Total Direct and Indirect Costs (G + H)</td>
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<tr>
<td>J, Fee</td>
<td></td>
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<tr>
<td>K, Total Costs and Fee (I + J)</td>
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</tbody>
</table>
R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

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

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

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

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**  
   - **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.**  
   - **Add Attachment**  
   - **Delete Attachment**  
   - **View Attachment**

6. **Select Agent Research**  
   - **Add Attachment**  
   - **Delete Attachment**  
   - **View Attachment**

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

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

9. **Letters of Support**  
   - **Required for R36 applications.**
   - **Add Attachment**  
   - **Delete Attachment**  
   - **View Attachment**

10. **Resource Sharing Plan(s)**  
    - **Add Attachment**  
    - **Delete Attachment**  
    - **View Attachment**

11. **Other Plan(s)**

12. **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
13. **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 funding opportunity as allowed or required.**
    - **Allows for up to 10 appendices. See Application Guide and funding opportunity 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: 11/30/2025

* 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
  - [x] No

* 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

* 1d. Is your small business a Faculty or Student-Owned entity?
  - [x] 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:

* 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 website: http://www.sba.gov
  - [ ] Yes
  - [ ] No

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

* 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:

* 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

* 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

**FORMS-G: New question.**

* 8. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase III/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.
  - [ ] Attach File: Required for Phase II, Direct Phase II, Phase IIB, Phase I/II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.
### SBIR/STTR Information

#### SBIR-Specific Questions:

**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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<tr>
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</tbody>
</table>

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

* 10. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

#### STTR-Specific Questions:

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

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

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

* 13. Provide UEI of non-profit research partner for STTR.

[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?  
   - [X] 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.

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?  
  - [X] Yes
  - [ ] No

- Is the Project Exempt from Federal regulations?  
  - [X] Yes
  - [ ] No

- Exemption number:

Information populated from R&R Other Project Information form.

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 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

Deferred Onset Study(ies)

Cannot add a Deferred 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 must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

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

Section 1 - Basic Information

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

1.2. * Is this Study Exempt from Federal Regulations?

1.3. Exemption Number

1.4. * Clinical Trial Questionnaire

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

2.2. Eligibility Criteria

2.3. Age Limits

2.3.a. Inclusion of Individuals Across the Lifespan

2.4. Inclusion of Women and Minorities

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s)
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.

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.

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

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</table>
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).

Single IRB plan attachment

Not 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 funding 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 funding opportunity 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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</thead>
<tbody>
<tr>
<td></td>
<td>Up to 200 characters.</td>
<td>Up to 1,000 characters.</td>
</tr>
</tbody>
</table>

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

4.1.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>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Dropdown list: Primary; Secondary; and Other</td>
</tr>
<tr>
<td>Time Frame</td>
<td>Up to 255 characters.</td>
</tr>
<tr>
<td>Brief Description</td>
<td>Up to 999 characters.</td>
</tr>
</tbody>
</table>

4.3. Statistical Design and Power

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

4.4. Subject Participation Duration

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

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

- Yes
- No

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 funding opportunity.
PHS Assignment Request Form

Funding Opportunity Number: Pre-populated from funding opportunity information.

Funding Opportunity Title: Pre-populated from funding opportunity information.

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.
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.

Entry is limited to 1000 characters.

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.