Grant applications to NIH for due dates on/after May 25, 2020 must use application form packages with a “FORMS-F” Competition ID.

This document summarizes the form updates to be included in FORMS-F application packages.

## Summary

<table>
<thead>
<tr>
<th>Form</th>
<th>Changes</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SF424 (R&amp;R)</strong></td>
<td>• Updated Expiration Date</td>
<td>3</td>
</tr>
<tr>
<td><strong>PHS 398 Cover Page Supplement</strong></td>
<td>• Updated Expiration Date</td>
<td>5</td>
</tr>
</tbody>
</table>
|                                                 | • Added Human Fetal Tissue Section including question - “Does the proposed project involve human fetal tissue obtained from elective abortions?”  
<p>|                                                 | o If Yes, two new attachments are requested  |
|                                                 | 1. HFT Compliance Assurance                 |      |
|                                                 | 2. HFT Sample IRB Consent Form               |      |
|                                                 | • Renumbered form fields, as needed          |      |
| <strong>R&amp;R Other Project Information</strong>              | • Updated Expiration Date                    | 7    |
| <strong>Project/Performance Site Locations(s)</strong>       | • Updated Expiration Date                    | 8    |
| <strong>R&amp;R Senior/Key Person Profile (Expanded)</strong>   | • Updated Expiration Date                    | 9    |
| <strong>R&amp;R Budget</strong>                                 | • Updated Expiration Date                    | 10   |
| <strong>R&amp;R Subaward Budget Attachment Form</strong>        | • Updated Expiration Date                    | 14   |
| <strong>PHS 398 Modular Budget</strong>                     | • Updated Expiration Date                    | 15   |
| <strong>PHS 398 Training Budget</strong>                    | • Updated Expiration Date                    | 16   |
| <strong>PHS 398 Training Subaward Budget Attachment(s)</strong> | • Updated Expiration Date                | 18   |
| <strong>PHS Additional Indirect Costs Form</strong>         | • Updated Expiration Date                    | 19   |
| <strong>SF 424C Budget Information – Construction Programs</strong> | • No changes                              | 21   |
| <strong>PHS 398 Research Plan</strong>                      | • Updated Expiration Date                    | 22   |
| <strong>PHS 398 Career Development Award Supplemental Form</strong> | • Updated Expiration Date                | 23   |
|                                                 | • Added new attachment titled “Description of Candidate’s Contribution to Program Goals” to the Environment and Institutional Commitment to Candidate Section |      |
|                                                 | • Renumbered form fields, as needed          |      |
| <strong>PHS 398 Research Training Program Plan</strong>     | • Updated Expiration Date                    | 25   |
| <strong>PHS Fellowship Supplemental Form</strong>            | • Updated Expiration Date                    | 26   |
|                                                 | • Added new attachment titled “Description of Candidate’s Contribution to Program Goals” to the Institutional Environment and Commitment to Training Section |      |
|                                                 | • Renumbered form fields, as needed          |      |</p>
<table>
<thead>
<tr>
<th>SBIR/STTR Information</th>
<th>Updated Expiration Date</th>
<th>Added Phase IIC as an Application Type option</th>
<th>Note: “Phase IIC” was added to meet the needs of another federal agency; NIH has no plans to allow this option</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHS Human subjects and Clinical Trials Information</td>
<td>Updated Expiration Date</td>
<td>Reworked landing page to allow an answer and supporting explanation for the question “Does any of the proposed research in the application involve human specimens and/or data?” even when human subjects studies are also present</td>
<td></td>
</tr>
<tr>
<td><strong>Study record changes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Defaulted Clinical Trial Questionnaire question “1.4.a Does the study involve human participants?” to Yes, since study records are only available when the answer to the “Are Human Subjects Involved?” question on the R&amp;R Other Project Information form is Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” and “Inclusion of Women and Minorities”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”</td>
<td></td>
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</tr>
<tr>
<td>• Added “Inclusion Enrollment Report Title” field to the Inclusion Enrollment Report</td>
<td></td>
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<tr>
<td>• Removed “Brief Summary” attachment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Renamed “Narrative Study Description” attachment to “Detailed Description”</td>
<td></td>
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</tr>
<tr>
<td>• Added new question and checkbox – “Is this an applicable clinical trial under FDAAA?”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Renumbered form fields, as needed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHS Assignment Request form</td>
<td>Updated Expiration Date</td>
<td>Clarified instruction text displayed on form</td>
<td>Changed several field labels</td>
</tr>
<tr>
<td>• Removed fields</td>
<td></td>
<td></td>
<td>o Do Not Assign to Awarding Components</td>
</tr>
<tr>
<td>• Added “Rationale for assignment suggestions” text box</td>
<td></td>
<td></td>
<td>o Do Not Assign to Study Sections</td>
</tr>
</tbody>
</table>
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: __________________________
Street1: ____________________________
City: __________________________
State: __________________________
Country: __________________________
Phone Number: ______________________
Fax Number: _______________________
Email: ___________________________

6. EMPLOYER IDENTIFICATION (EIN) or (TIN):

7. TYPE OF APPLICANT:
Other (Specify): ____________________
Women Owned
Socially and Economically Disadvantaged

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

Is this application being submitted to other agencies?
- Yes
- No
What other Agencies?

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date:
Ending Date:

13. CONGRESSIONAL DISTRICT OF APPLICANT

OMB Number: 4040-0001
Expiration Date: MM/DD/YYYY

Updated Expiration Date:
New date from OMB pending.
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: [ ] First Name: [ ] Middle Name: [ ] Last Name: [ ] Suffix: [ ]
Position/Title: [ ] Organization Name: [ ]
Department: [ ] Division: [ ] Street1: [ ]
Street2: [ ] City: [ ] County / Parish: [ ] Province: [ ]
State: [ ] Country: [USA: UNITED STATES] ZIP / Postal Code: [ ]
Phone Number: [ ] Fax Number: [ ] Email: [ ]

15. ESTIMATED PROJECT FUNDING

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: [ ]
b. 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)

[ ] I agree

*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

Prefix: [ ] First Name: [ ] Middle Name: [ ] Last Name: [ ] Suffix: [ ]
Position/Title: [ ] Organization: [ ]
Department: [ ] Division: [ ] Street1: [ ]
Street2: [ ] City: [ ] County / Parish: [ ] Province: [ ]
State: [ ] Country: [USA: UNITED STATES] ZIP / Postal Code: [ ]
Phone Number: [ ] Fax Number: [ ] Email: [ ]

Signature of Authorized Representative: [ ] Date Signed: [ ]

20. Pre-application

21. Cover Letter Attachment
### 1. Vertebrate Animals Section

Are vertebrate animals euthanized?  
- [ ] Yes  
- [x] No

If "Yes" to euthanasia:  
Is method consistent with American Veterinary Medical Association (AVMA) guidelines?  
- [ ] Yes  
- [x] No

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

---

### 2. Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?*  
- [ ] Yes  
- [ ] No

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

<table>
<thead>
<tr>
<th>Budget Period</th>
<th>Anticipated Amount ($)</th>
<th>Source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

---

### 3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells?*  
- [ ] Yes  
- [ ] No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

- [ ] Specific stem cell line cannot be referenced at this time. One from the registry will be used.

**Cell Line(s) (Example: 0004):**

---

### 4. Human Fetal Tissue Section

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

If "yes" then provide the HFT Compliance Assurance.

[Add Attachment]  [Delete Attachment]  [View Attachment]

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

[Add Attachment]  [Delete Attachment]  [View Attachment]
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: 

Suffix: 

☐ Change of Grantee Institution

*Name of former institution: 

---
1. Are Human Subjects Involved?  
   - Yes  
   - No

1.a. If YES to Human Subjects
   - Is the Project Exempt from Federal regulations?  
     - Yes  
     - No
   - If yes, check appropriate exemption number.  
     - 1  
     - 2  
     - 3  
     - 4  
     - 5  
     - 6  
     - 7  
     - 8
   - If no, is the IRB review Pending?  
     - Yes  
     - No
   - IRB Approval Date: ________________  
   - Human Subject Assurance Number: ________________

2. Are Vertebrate Animals Used?  
   - Yes  
   - No

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

3. Is proprietary/privileged information included in the application?  
   - Yes  
   - No

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment?  
   - Yes  
   - No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?  
   - Yes  
   - No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?  
   - Yes  
   - No

5.a. If yes, please explain:

6. Does this project involve activities outside of the United States or partnerships with international collaborators?  
   - Yes  
   - No

6.a. If yes, identify countries: ____________________________

6.b. Optional Explanation: ____________________________

7. Project Summary/Abstract: ____________________________

8. Project Narrative: ____________________________

9. Bibliography & References Cited: ____________________________

10. Facilities & Other Resources: ____________________________

11. Equipment: ____________________________

12. Other Attachments: ____________________________
<table>
<thead>
<tr>
<th>Location</th>
<th>Organization Name</th>
<th>DUNS Number</th>
<th>Street1</th>
<th>Street2</th>
<th>City</th>
<th>County</th>
<th>State</th>
<th>Province</th>
<th>Country</th>
<th>ZIP / Postal Code</th>
<th>Congressional District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
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<td>Additional</td>
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</tbody>
</table>
To ensure proper performance of this form; after adding 20 additional Senior/Key Persons; please save your application, close the Adobe Reader, and reopen it.
**A. Senior/Key Person**

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First</th>
<th>Middle</th>
<th>Last</th>
<th>Suffix</th>
<th>Base Salary ($)</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Cal.</td>
<td>Acad. Sum.</td>
<td></td>
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</tr>
</tbody>
</table>

**Project Role:** PD/PI

**Additional Senior Key Persons:**

Total Senior/Key Person

**B. Other Personnel**

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td>Cal.</td>
<td>Acad. Sum.</td>
<td></td>
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</tbody>
</table>

- Post Doctoral Associates
- Graduate Students
- Undergraduate Students
- Secretarial/Clerical

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)
C. Equipment Description

List items and dollar amount for each item exceeding $5,000

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

Additional Equipment: [Add Attachment] [Delete Attachment] [View Attachment]

Total funds requested for all equipment listed in the attached file

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

D. Travel

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

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

2. Foreign Travel Costs

Total Travel Cost

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

E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

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

2. Stipends

<p>| |</p>
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3. Travel

<p>| |</p>
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4. Subsistence

<p>| |</p>
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</table>

5. Other

<p>| |</p>
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</table>

Number of Participants/Trainees

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

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<tr>
<th>No.</th>
<th>Item</th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Materials and Supplies</td>
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</tr>
<tr>
<td>2.</td>
<td>Publication Costs</td>
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</tr>
<tr>
<td>3.</td>
<td>Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8.</td>
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<tr>
<td>9.</td>
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<tr>
<td>10.</td>
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</table>

Total Other Direct Costs

**G. Direct Costs**

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

Total Direct Costs (A thru F)

**H. Indirect Costs**

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

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**

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

**K. Total Costs and Fee**

Total Costs and Fee (I + J)

**L. Budget Justification**

(Only attach one file.)

[Add Attachment] [Delete Attachment] [View Attachment]
## Section A, Senior/Key Person

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

## Section B, Other Personnel

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

## Section C, Equipment

<table>
<thead>
<tr>
<th>Section D, Travel</th>
</tr>
</thead>
</table>

1. Domestic

2. Foreign

## Section E, Participant/Trainee Support Costs

<table>
<thead>
<tr>
<th>Section F, Other Direct Costs</th>
</tr>
</thead>
</table>

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

6. Number of Participants/Trainees

<table>
<thead>
<tr>
<th>Section G, Direct Costs (A thru F)</th>
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</table>

<table>
<thead>
<tr>
<th>Section H, Indirect Costs</th>
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</table>

<table>
<thead>
<tr>
<th>Section I, Total Direct and Indirect Costs (G + H)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Section J, Fee</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Section K, Total Costs and Fee (I + J)</th>
</tr>
</thead>
</table>
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
# PHS 398 Modular Budget

**Budget Period:** 1

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>End Date:</th>
</tr>
</thead>
</table>

## A. Direct Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
<th>Direct Cost less Consortium Indirect (F&amp;A)</th>
<th>Consortium Indirect (F&amp;A)</th>
<th>Total Direct Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
</tr>
</tbody>
</table>

## B. Indirect (F&A) Costs

<table>
<thead>
<tr>
<th>Indirect (F&amp;A) Type</th>
<th>Indirect (F&amp;A) Rate (%)</th>
<th>Indirect (F&amp;A) Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Cognizant Agency (Agency Name, POC Name and Phone Number)</th>
<th>Indirect (F&amp;A) Rate Agreement Date</th>
<th>Total Indirect (F&amp;A) Costs</th>
</tr>
</thead>
</table>

## C. Total Direct and Indirect (F&A) Costs (A + B)

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
</tr>
</tbody>
</table>

## Cumulative Budget Information

### 1. Total Costs, Entire Project Period

- **Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period**: $0.00
- **Section A, Total Consortium Indirect (F&A) for Entire Project Period**: $0.00
- **Section A, Total Direct Costs for Entire Project Period**: $0.00
- **Section B, Total Indirect (F&A) Costs for Entire Project Period**: $0.00
- **Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period**: $0.00

### 2. Budget Justifications

- **Personnel Justification**: Add Attachment
- **Consortium Justification**: Add Attachment
- **Additional Narrative Justification**: Add Attachment
# A. Stipends, Tuition/Fees

<table>
<thead>
<tr>
<th>Number of Trainees</th>
<th>Stipends Requested ($)</th>
<th>Tuition/Fees Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Time Undergraduate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Term Undergraduate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number Per Stipend Level:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-Year/Soph.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Junior/Senior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Predoctoral: Single Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dual Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Predoctoral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postdoctoral: Number Per Stipend Level:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-degree Seeking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree Seeking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Postdoctoral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Totals: | | | | | | | | |

**Total Stipends + Tuition/Fees Requested**

# B. Other Direct Costs

- Trainee Travel
- Training Related Expenses
- Total Direct Costs from R&R Budget Form (if applicable)
- Consortium Training Costs (if applicable)

**Total Other Direct Costs Requested**

# C. Total Direct Costs Requested (A + B)

# D. Indirect (F&A) Costs

<table>
<thead>
<tr>
<th>Indirect (F&amp;A) Type</th>
<th>Indirect (F&amp;A) Rate (%)</th>
<th>Indirect (F&amp;A) Base</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Indirect (F&A) Costs Requested**

# E. Total Direct and Indirect (F&A) Costs Requested (C + D)

# F. Budget Justification
## A. Stipends, Tuition/Fees

<table>
<thead>
<tr>
<th></th>
<th>Stipends Requested ($)</th>
<th>Tuition/Fees Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undergraduate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Predoctoral:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dual Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Predoctoral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postdoctoral:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Degree Seeking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree Seeking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Postdoctoral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Stipends + Tuition/Fees Requested</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## B. Other Direct Costs

<table>
<thead>
<tr>
<th></th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trainee Travel</td>
<td></td>
</tr>
<tr>
<td>Training Related Expenses</td>
<td></td>
</tr>
<tr>
<td>Total Direct Costs from R&amp;R Budget Form (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Consortium Training Costs (if applicable)</td>
<td></td>
</tr>
<tr>
<td><strong>Total Other Direct Costs Requested</strong></td>
<td></td>
</tr>
</tbody>
</table>

## C. Total Direct Costs Requested (A + B)


## D. Total Indirect (F&A) Costs Requested


## E. Total Direct and Indirect (F&A) Costs Requested (C + D)


TRAINING SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions:
This form allows you to attach a PHS 398 Training Budget form for each subaward/consortium associated with your application. Use the "Click here to extract the PHS 398 Training Subaward Attachment" button to extract a blank copy of the PHS 398 Training Budget form, complete the form in accordance with the agency instructions, and attach the completed form using one of the "Add Attachment" buttons.

Important:
Attach Training Subaward Budget forms, using the blocks below. Remember that the files you attach must be PHS 398 Training Budget PDF forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

Click here to extract the PHS 398 Training Subaward Attachment

| Attach Training Subaward Budget 1 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 2 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 3 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 4 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 5 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 6 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 7 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 8 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 9 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 10 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 11 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 12 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 13 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 14 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 15 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 16 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 17 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 18 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 19 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 20 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 21 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 22 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 23 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 24 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 25 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 26 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 27 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 28 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 29 | Add Attachment | Delete Attachment | View Attachment |
| Attach Training Subaward Budget 30 | Add Attachment | Delete Attachment | View Attachment |
### PHS Additional Indirect Costs - Budget Period 1

**ORGANIZATIONAL DUNS:** Enter name of Organization:  

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

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

**Indirect Costs**

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

**Total Indirect Costs**  

**Budget Justification**

(Only attach one file.)  

![Add Attachment](#) ![Delete Attachment](#) ![View Attachment](#)

**Updated Expiration Date:**  

New date from OMB pending.
<table>
<thead>
<tr>
<th>Indirect Costs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Totals ($)</td>
<td></td>
</tr>
</tbody>
</table>
### BUDGET INFORMATION - Construction Programs

**NOTE:** Certain Federal assistance programs require additional computations to arrive at the Federal share of project costs eligible for participation. If such is the case, you will be notified.

<table>
<thead>
<tr>
<th>COST CLASSIFICATION</th>
<th>a. Total Cost</th>
<th>b. Costs Not Allowable for Participation</th>
<th>c. Total Allowable Costs (Columns a-b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Administrative and legal expenses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Land, structures, rights-of-way, appraisals, etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Relocation expenses and payments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Architectural and engineering fees</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Other architectural and engineering fees</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Project inspection fees</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Site work</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Demolition and removal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Construction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Miscellaneous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. SUBTOTAL (sum of lines 1-11)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Contingencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. SUBTOTAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Project (program) income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. TOTAL PROJECT COSTS (subtract #15 from #14)</td>
<td>$_____</td>
<td>$_____</td>
<td>$_____</td>
</tr>
</tbody>
</table>

**FEDERAL FUNDING**

17. Federal assistance requested, calculate as follows: (Consult Federal agency for Federal percentage share.) Enter eligible costs from line 16c Multiply X _____ % $_____

Enter the resulting Federal share.
## Introduction

1. Introduction to Application (for Resubmission and Revision applications)

## Research Plan Section

2. Specific Aims

3. *Research Strategy

4. Progress Report Publication List

## Other Research Plan Section

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan

8. Consortium/Contractual Arrangements

9. Letters of Support

10. Resource Sharing Plan(s)

11. Authentication of Key Biological and/or Chemical Resources

## Appendix

12. Appendix
# PHS 398 Career Development Award Supplemental Form

**Introduction**

1. Introduction to Application  
   (for Resubmission and Revision applications)

**Candidate Section**

2. Candidate Information and Goals for Career Development

**Research Plan Section**

3. Specific Aims

4. * Research Strategy

5. Progress Report Publication List  
   (for Renewal applications)

6. Training in the Responsible Conduct of Research

**Other Candidate Information Section**

7. Candidate's Plan to Provide Mentoring

**Mentor, Co-Mentor, Consultant, Collaborators Section**

8. Plans and Statements of Mentor and Co-Mentor(s)

9. Letters of Support from Collaborators, Contributors, and Consultants

**Environment and Institutional Commitment to Candidate Section**

10. Description of Institutional Environment

11. Institutional Commitment to Candidate's Research Career Development

12. Description of Candidate's Contribution to Program Goals

**Other Research Plan Sections**

13. Vertebrate Animals

14. Select Agent Research

15. Consortium/Contractual Arrangements

16. Resource Sharing

17. Authentication of Key Biological and/or Chemical Resources

---

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Introduction** | 1. Introduction to Application  
   (for Resubmission and Revision applications) |
| **Candidate Section** | 2. Candidate Information and Goals for Career Development |
| **Research Plan Section** | 3. Specific Aims  
4. * Research Strategy  
5. Progress Report Publication List  
   (for Renewal applications)  
6. Training in the Responsible Conduct of Research |
| **Other Candidate Information Section** | 7. Candidate's Plan to Provide Mentoring |
| **Mentor, Co-Mentor, Consultant, Collaborators Section** | 8. Plans and Statements of Mentor and Co-Mentor(s)  
9. Letters of Support from Collaborators, Contributors, and Consultants |
| **Environment and Institutional Commitment to Candidate Section** | 10. Description of Institutional Environment  
11. Institutional Commitment to Candidate's Research Career Development  
12. Description of Candidate's Contribution to Program Goals  
   Added "Description of Candidate's Contribution to Program Goals" attachment.  
   Renumbered subsequent form fields. |
| **Other Research Plan Sections** | 13. Vertebrate Animals  
14. Select Agent Research  
15. Consortium/Contractual Arrangements  
16. Resource Sharing  
17. Authentication of Key Biological and/or Chemical Resources |
* Citizenship

19. * U.S. Citizen or Non-Citizen National?  □ Yes  □ No

If no, select most appropriate Non-U.S. Citizen option

□ With a Permanent U.S. Resident Visa
□ With a Temporary U.S. Visa
□ Not Residing in the U.S.

If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here: □
## Introduction

1. Introduction to Application (for Resubmission and Revision applications)

## Training Program Section

2. * Program Plan

3. Plan for Instruction in the Responsible Conduct of Research

4. Plan for Instruction in Methods for Enhancing Reproducibility

5. Multiple PD/PI Leadership Plan (if applicable)

6. Progress Report (for Renewal applications)

## Faculty, Trainees and Training Record Section

7. Participating Faculty Biosketches

8. Letters of Support

9. Data Tables

## Other Training Program Section

10. Vertebrate Animals

11. Select Agent Research

12. Consortium/Contractual Arrangements

## Appendix

13. Appendix
**PHS Fellowship Supplemental Form**

**Introduction**
1. Introduction to Application (for Resubmission applications)
   - Add Attachment
   - Delete Attachment
   - View Attachment

**Fellowship Applicant Section**
2. Applicant's Background and Goals for Fellowship Training
   - Add Attachment
   - Delete Attachment
   - View Attachment

**Research Training Plan Section**
3. Specific Aims
   - Add Attachment
   - Delete Attachment
   - View Attachment

4. Research Strategy
   - Add Attachment
   - Delete Attachment
   - View Attachment

5. Respective Contributions
   - Add Attachment
   - Delete Attachment
   - View Attachment

6. Selection of Sponsor and Institution
   - Add Attachment
   - Delete Attachment
   - View Attachment

7. Progress Report Publication List (for Renewal applications)
   - Add Attachment
   - Delete Attachment
   - View Attachment

8. Training in the Responsible Conduct of Research
   - Add Attachment
   - Delete Attachment
   - View Attachment

**Sponsor(s), Collaborator(s), and Consultant(s) Section**
9. Sponsor and Co-Sponsor Statements
   - Add Attachment
   - Delete Attachment
   - View Attachment

10. Letters of Support from Collaborators, Contributors, and Consultants
    - Add Attachment
    - Delete Attachment
    - View Attachment

**Institutional Environment and Commitment to Training Section**
11. Description of Institutional Environment and Commitment to Training
    - Add Attachment
    - Delete Attachment
    - View Attachment

12. Description of Candidate's Contribution to Program Goals
    - Added "Description of Candidate's Contribution to Program Goals" attachment.

**Other Research Training Plan Section**

**Vertebrate Animals**
The following item is taken from the Research & Related Other Project Information form and repeated here for your reference. Any change to this item must be made on the Research & Related Other Project Information form.

Are Vertebrate Animals Used?  □ Yes  □ No

13. Are vertebrate animals euthanized?  □ Yes  □ No

If "Yes" to euthanasia
   - Is method consistent with American Veterinary Medical Association (AVMA) guidelines?  □ Yes  □ No

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

14. Vertebrate Animals
    - Add Attachment
    - Delete Attachment
    - View Attachment

---

Updated Expiration Date. New date from OMB pending.
### Other Research Training Plan Information

15. Select Agent Research

16. Resource Sharing Plan

17. Authentication of Key Biological and/or Chemical Resources

### Additional Information Section

18. Human Embryonic Stem Cells

* 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, please 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):**

<table>
<thead>
<tr>
<th>Cell Line</th>
<th>Registration Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

19. Alternate Phone Number:

20. Degree Sought During Proposed Award:

<table>
<thead>
<tr>
<th>Degree</th>
<th>If &quot;other&quot;, indicate degree type:</th>
<th>Expected Completion Date (MM/YYYY):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

21. * Field of Training for Current Proposal:

22. * Current or Prior Kirschstein-NRSA Support?  

  - [ ] Yes  
  - [ ] No

If yes, identify current and prior Kirschstein-NRSA support below:

<table>
<thead>
<tr>
<th>* Level</th>
<th>* Type</th>
<th>Start Date (if known)</th>
<th>End Date (if known)</th>
<th>Grant Number (if known)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

23. * Applications for Concurrent Support  

  - [ ] Yes  
  - [ ] No

If yes, describe in an attached file:

Add Attachment  
Delete Attachment  
View Attachment

24. * Citizenship:

  - U.S. Citizen  
  - Non-U.S. Citizen

  - [ ] Yes  
  - [ ] No

  With a Permanent U.S. Resident Visa

  With a Temporary U.S. Visa

If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here:

25. Change of Sponsoring Institution

<table>
<thead>
<tr>
<th>Name of Former Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Budget Section

#### All Fellowship Applicants:

26. * Tuition and Fees:

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6 (when applicable)</th>
</tr>
</thead>
</table>

#### Senior Fellowship Applicants Only:

27. Present Institutional Base Salary:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Academic Period</th>
<th>Number of Months</th>
</tr>
</thead>
</table>

28. Stipends/Salary During First Year of Proposed Fellowship:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Number of Months</th>
</tr>
</thead>
</table>

   a. Federal Stipend Requested:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Number of Months</th>
</tr>
</thead>
</table>

   b. Supplementation from Other Sources:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Number of Months</th>
</tr>
</thead>
</table>

   Type (e.g., sabbatical leave, salary)

   Source

### Appendix

29. Appendix

[Add Attachments]  [Delete Attachments]  [View Attachments]
SBIR/STTR Information

* Agency to which you are applying (select only one)
- [ ] DOE
- [ ] HHS
- [ ] USDA
- [ ] Other:

* SBC Control ID: ____________________________(This 9 digit code is obtained from the Small Business Administration)

* Program Type (select only one)
- [X] 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: ____________________________

* Agency Topic/Subtopic: ____________________________

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

[ ] 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?

[ ] 1b. Anticipated Number of personnel to be employed at your organization at the time of award.

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

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

[ ] 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?
   * 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 web site: http://www.sba.gov

[ ] 4. Will all research and development on the project be performed in its entirety in the United States?
   * If no, provide an explanation in an attached file.
   * Explanation: ____________________________

[ ] 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?
   * 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)?

[ ] 7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase III/ Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.
   * Attach File: ____________________________

OMB Number: 4040-0001
Expiration Date: MM/DD/YYYY
Updated Expiration Date.
New date from OMB pending.

NIH Office of Extramural Research
Preview of Forms in FORMS-F Series
### SBIR/STTR Information

#### SBIR-Specific Questions:

* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment.

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

#### STTR-Specific Questions:

* 10. Please indicate whether the answer to BOTH of the following questions is TRUE:

- 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
- Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?

* 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

* 12. Provide DUNS Number of non-profit research partner for STTR.
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

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


Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Delayed Onset Study(ies)

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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</tr>
</tbody>
</table>
**Study Record: PHS Human Subjects and Clinical Trials Information**

OMB Number: 0925-0001
Expiration Date: MM/DD/YYYY

* Always required field

### Section 1 - Basic Information

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

1.2. *Is this Study Exempt from Federal Regulations?*

   - Yes
   - No

1.3. Exemption Number

   1 2 3 4 5 6 7 8

1.4. *Clinical Trial Questionnaire*

   If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

   1.4.a. Does the study involve human participants?  
   ☒ Yes  ☐ No

   1.4.b. Are the participants prospectively assigned to an intervention?  
   ☒ Yes  ☐ No

   1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?  
   ☒ Yes  ☐ No

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

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

### Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

2.2. Eligibility Criteria

2.3. Age Limits

   - Minimum Age
   - Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan

   Separated "Inclusion of Women, Minorities, and Children" attachment into two attachments - "Inclusion of Individuals Across the Lifespan" and "Inclusion of Women and Minorities."

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

   Renamed "Enrollment of First Subject" field to "Enrollment of First Participant."

2.9. Inclusion Enrollment Report(s)

   Added field number for Inclusion Enrollment Report(s).

Add Inclusion Enrollment Report(s)
Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

2. * Using an Existing Dataset or Resource
   - Yes
   - No

3. * Enrollment Location Type
   - Domestic
   - Foreign

4. Enrollment Country(ies)

5. Enrollment Location(s)

6. Comments
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<th>Racial Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Total</th>
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<td>Total</td>
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</tr>
</tbody>
</table>

Report 1 of 1
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

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

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?
- Yes
- No

3.5. Overall Structure of the Study Team

Section 4 - Protocol Synopsis

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

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

4.1.d. Study Phase

Is this an NIH-defined Phase III clinical trial?
- Yes
- No

4.1.e. Intervention Model

4.1.f. Masking
- Yes
- No
- Participant
- Care Provider
- Investigator
- Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Time Frame</th>
<th>Brief Description</th>
</tr>
</thead>
</table>

4.3. Statistical Design and Power

4.4. Subject Participation Duration

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

4.6. Is this an applicable clinical trial under FDAAA?  
☐ Yes  ☐ No  

4.7. Dissemination Plan

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments
PHS Assignment Request Form

Funding Opportunity Number:  

Funding Opportunity Title:  

Awarding Component Assignment Suggestions (optional)  

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

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

Suggested Awarding Components: 

Study Section Assignment Suggestions (optional)  

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

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

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

Suggested Study Sections: 


Rationale for assignment suggestions (optional)  

Entry is limited to 1000 characters.
PHS Assignment Request Form

List individuals who should not review your application and why (optional)  
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

1 2 3 4 5