Annotated Form Set for NIH Grant Applications: FORMS-F Series

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

NIH application form packages include a subset of the forms included in this resource. You only need to complete the forms provided to you with a specific funding opportunity announcement (FOA).

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<td>• Added Human Fetal Tissue Section including question - “Does the proposed</td>
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<td>project involve human fetal tissue obtained from elective abortions?”</td>
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<td>o If Yes, two new attachments are requested</td>
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<td>23</td>
</tr>
<tr>
<td></td>
<td>• Added new attachment titled “Description of Candidate’s Contribution to</td>
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<td></td>
<td>Program Goals” to the Environment and Institutional Commitment to</td>
<td></td>
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<td></td>
<td>Candidate Section</td>
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<td></td>
<td>• Renumbered form fields, as needed</td>
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<tr>
<td>PHS 398 Research Training Program Plan</td>
<td>• Updated Expiration Date</td>
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<td>PHS Fellowship Supplemental Form</td>
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<td>26</td>
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<td>• Added new attachment titled “Description of Candidate’s Contribution to</td>
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<td>Program Goals” to the Institutional Environment and Commitment to</td>
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<td>Training Section</td>
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<td></td>
<td>• Renumbered form fields, as needed</td>
<td></td>
</tr>
</tbody>
</table>
| SBIR/STTR Information | Updated Expiration Date  
| Added Phase IIC as an Application Type option  
| Note: “Phase IIC” was added to meet the needs of another federal agency; NIH has no plans to allow this option |

| PHS Human subjects and Clinical Trials Information | Updated Expiration Date  
| 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?” regardless of answer to human subjects involvement question (previously only available if human subjects involvement was no)  
| **Study record changes**  
| 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&R Other Project Information form is Yes  
| Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” and “Inclusion of Women and Minorities”  
| Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”  
| Added “Inclusion Enrollment Report Title” field to the Inclusion Enrollment Report  
| Removed “Brief Summary” attachment  
| Renamed “Narrative Study Description” attachment to “Detailed Description”  
| Added new question and checkbox – “Is this an applicable clinical trial under FDAAA?”  
| Renumbered form fields, as needed |

| PHS Assignment Request Form | Updated Expiration Date  
| Clarified instruction text displayed on form  
| Changed several field labels  
| Removed fields  
| Do Not Assign to Awarding Components  
| Do Not Assign to Study Sections  
| Added “Rationale for assignment suggestions” text box |

**Notes:**
- The funding opportunity announcement, notices in the NIH Guide, and the application guide define the official application requirements. This resource is meant to complement, not replace, those documents.
- The actual display of the forms depends on your submission method (ASSIST, system-to-system solution, or Workspace). The same form content requirements apply regardless of submission method.
- Registration in multiple systems is required prior to submission, see How to Apply - Application Guide.
1. **TYPE OF SUBMISSION**  
   - Pre-application  
   - Application  
   - Changed/Corrected Application

2. **DATE SUBMITTED**  
   - Applicant Identifier

3. **DATE RECEIVED BY STATE**  
   - State Application Identifier

4. **a. Federal Identifier**  
   - If New (box 8), leave blank. If Revision/Resubmission/Renewal (box 8), use number and serial # of previous NIH grant/application # (e.g., CA987654 from 1R01CA987654-01).

5. **APPLICANT INFORMATION**  
   - Organizational DUNS:
   - Legal Name:
   - Department:
   - Division:
   - Street1:
   - Street2:
   - City:
   - County / Parish:
   - State:
   - Province:
   - ZIP / Postal Code:
   - Country:

6. **EMPLOYER IDENTIFICATION (EIN) or (TIN):**  
   - Non-US organizations use 44444444.

7. **TYPE OF APPLICANT:**  
   - Please select one of the following

8. **TYPE OF APPLICATION:**  
   - Women Owned
   - Socially and Economically Disadvantaged

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**

   - NIH Office of Extramural Research
   - FORMS-F Series (Updated July 6, 2021)
   - Page 3
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: ___________________  First Name: ___________________  Middle Name: ___________________

Last Name: ___________________  PD/PI first/last name should match name on file for Commons ID provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) form.  Suffix: ___________________

Position/Title: ___________________

Organization Name: ___________________

Department: ___________________

Street1: ___________________

Street2: ___________________

City: ___________________ County / Parish: ___________________

State: ___________________  Province: ___________________

Country: ___________________  USA: UNITED STATES  ZIP / Postal Code: ___________________

Phone Number: ___________________  Fax Number: ___________________

Email: ___________________

15. ESTIMATED PROJECT FUNDING

Manually enter estimated project funding amounts.

a. Total Federal Funds Requested

b. Total Non-Federal Funds

c. Total Federal & Non-Federal Funds

d. Estimated Program Income

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES □  THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE: ___________________

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

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

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

19. Authorized Representative

Prefix: ___________________  First Name: ___________________  Middle Name: ___________________

Last Name: ___________________  Suffix: ___________________

Position/Title: ___________________

Organization Name: ___________________

Department: ___________________  Division: ___________________

Street1: ___________________

Street2: ___________________

City: ___________________ County / Parish: ___________________

State: ___________________  Province: ___________________

Country: ___________________  USA: UNITED STATES  ZIP / Postal Code: ___________________

Phone Number: ___________________  Fax Number: ___________________

Email: ___________________

Signature of Authorized Representative  Date Signed: ___________________

20. Pre-application

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
1. Vertebrate Animals Section
Are vertebrate animals euthanized? ☐ Yes ☐ No

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

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

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

2. Program Income Section

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

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

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

Form accommodates up to 10 budget periods. The number of program income budget periods must be less than or equal to the number of periods included in the budget form.

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ☐ Yes ☐ No

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

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

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

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Provide up to 200 cell lines.

4. Human Fetal Tissue Section

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

If "yes" then provide the HFT Compliance Assurance

Required if Yes. Cannot be included if No.

Add Attachment  Delete Attachment  View Attachment

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

Required if Yes. Cannot be included if No.

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

Change of PD/PI is not allowed for Revision or Career Development (K) applications.

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

Change of Grantee Institution is not allowed for Institution Training grant applications.

*Name of former institution: [ ]

If change of Grantee Institution box is checked, you must provide the name of former institution.
Project/Performance Site Location(s)

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

Organization Name: 
DUNS Number: 
* 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/additional-performance-site.htm
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Project Director/Principal Investigator

- **Prefix:**
- **First Name:**
- **Middle Name:**
- **Last Name:**
- **Suffix:**
- **Position/Title:**
- **Department:**
- **Organization Name:**
- **Division:**
- **Street1:**
- **City:**
- **State:**
- **Country:**
- **Phone Number:**
- **Fax Number:**
- **E-Mail:**
- **Credential, e.g., agency login:**
- **Province:**
- **Zip / Postal Code:**
- **State:**
- **County/Parish:**
- **City:**

**OAR IA Commons Username MUST BE SUPPLIED.** Contact PD/PI must be affiliated in Commons with applicant organization. Commons account designated on this form should not have both the PI and SO roles (if PD/PI also serves as SO, use a separate account for SO functions).

**ORCID ID must be associated with PD/PI eRA Commons Personal Profile of Fellowship and Career Development applications. Recommended for all.**

**Project Role:** PD/PI

**Degree Type:**

**Degree Year:**

**Attach Biographical Sketch**

**Attach Current & Pending Support**

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#### PROFILE - Senior/Key Person 1

- **Prefix:**
- **First Name:**
- **Middle Name:**
- **Last Name:**
- **Suffix:**
- **Position/Title:**
- **Department:**
- **Organization Name:**
- **Division:**
- **Street1:**
- **City:**
- **State:**
- **Country:**
- **Phone Number:**
- **Fax Number:**
- **E-Mail:**
- **Province:**
- **Zip / Postal Code:**

**For multiple PD/PI, you must use the PD/PI role, provide the eRA Commons username in the Credential field for all PD/PIs, and include a Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form. Targeting January 25, 2022 due dates, Credentials required for all Sr/Key (NOT-OD-21-109)**

**Required. Limited to 5 pages. Format page, instructions and samples:**

http://grants.nih.gov/grants/forms/biosketch.htm

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**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/additional-senior-key-person-profile.htm

---

To ensure proper performance of this form; after adding 20 additional Senior/Key Persons; please save your application, close the Adobe Reader, and reopen it.
**RESEARCH & RELATED BUDGET - Budget Period 1**

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

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

**ORGANIZATIONAL DUNS:** [ ]

**Enter name of Organization:** [ ]

**Project Subaward/Consortium**

Only the primary applicant organization should use Budget Type of Project (unless multi-project application).

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

**A. Senior/Key Person**

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

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

Project Role: [PD/PI]

Role must be PD/PI for the PD/PI (enter carefully, eRA will look for exact string match to PD/PI).

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

Additional Senior Key Persons:

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

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

**B. Other Personnel**

Aggregate information should be provided in section B and explained in Budget Justification.

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Project Role</th>
<th>Months</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>Graduate Students</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
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<td></td>
</tr>
</tbody>
</table>

You can name up to 6 additional Project Role categories. Once data for the first user-defined Project Role is entered, you will have the option to add another. If you run out of additional categories combine categories in a single row and explain what was included in the Budget Justification.

**Total Number Other Personnel**

**Total Other Personnel**

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

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

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

Once equipment data is entered, you will be able to add up to 9 more rows to this section for a total of 10 equipment items.

Additional Equipment:  

Total funds requested for all equipment listed in the attached file:

**Total Equipment**

### D. Travel

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

**Total Travel Cost**

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

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

2. Stipends

3. Travel

4. Subsistence

5. Other

**Number of Participants/Trainees**  

**Total Participant/Trainee Support Costs**
### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Examples of possible uses: Tuition Remission; Technical Assistance; Patient Care Costs</td>
<td></td>
</tr>
<tr>
<td>9. If proposing the use of human fetal tissue from elective abortions, you must include a &quot;Human Fetal Tissue Costs&quot; item (if no cost incurred, enter 0). Type the string as requested (without quotation marks). Systems will only pick up an exact match to the letters and spacing of the string (not case specific). The line item cannot be combined with any &quot;Other&quot; costs.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td></td>
</tr>
</tbody>
</table>

### G. Direct Costs

<table>
<thead>
<tr>
<th>Total Direct Costs (A thru F)</th>
<th>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>
</table>

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

### L. Budget Justification

(Only attach one file.)

Budget Justification is required and must cover all budget periods.

Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Totals ($)</th>
<th>Number of Participants/Trainees</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Senior/Key Person</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Other Personnel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Travel</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Domestic</td>
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<td></td>
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<td></td>
<td>2. Foreign</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Participant/Trainee Support Costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Tuition/Fees/Health Insurance</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>2. Stipends</td>
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<td></td>
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<td></td>
<td>3. Travel</td>
<td></td>
<td></td>
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<td></td>
<td>4. Subsistence</td>
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<td></td>
<td>5. Other</td>
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</tr>
<tr>
<td></td>
<td>6. Number of Participants/Trainees</td>
<td></td>
<td></td>
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<tr>
<td>F</td>
<td>Other Direct Costs</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>1. Materials and Supplies</td>
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<td></td>
<td>2. Publication Costs</td>
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<td></td>
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<td></td>
<td>3. Consultant Services</td>
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<td>4. ADP/Computer Services</td>
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<td>5. Subawards/Consortium/Contractual Costs</td>
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<td>6. Equipment or Facility Rental/User Fees</td>
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<td>7. Alterations and Renovations</td>
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<td></td>
<td>8. Other 1</td>
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<td>9. Other 2</td>
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<td></td>
<td>10. Other 3</td>
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</tr>
<tr>
<td>G</td>
<td>Direct Costs (A thru F)</td>
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<td></td>
</tr>
<tr>
<td>H</td>
<td>Indirect Costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>Total Direct and Indirect Costs (G + H)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>J</td>
<td>Fee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>K</td>
<td>Total Costs and Fee (I + J)</td>
<td></td>
<td></td>
</tr>
</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
The PHS 398 Modular Budget form cannot be used if the application requests >$250K in direct costs in any budget period, is submitted by a foreign institution, or proposes the use of human fetal tissue from elective abortions.

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

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

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

**Direct costs requested must be $250K or less per period to use Modular Budget form. Request in “modules” of $25K.**

**Some grant programs have limits on Total Direct Costs. Check announcement.**

### 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>
</table>

**Form allows for up to four F&A entries.**

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

**Indirect (F&A) Rate Agreement Date**

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

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

**Funds Requested ($)**

0.00

### Cumulative Budget Information

**System calculated.**

#### 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**
  

- **Section A, Total Direct Costs for Entire Project Period**
  
  $0.00

- **Section B, Total Indirect (F&A) Costs for Entire Project Period**
  

- **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 Per Stipend Level:</th>
<th></th>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>First-Year/Soph.</td>
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<tr>
<td>Junior/Senior</td>
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<td>Predoctorial</td>
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<td>Single Degree</td>
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<td>Total Predoctoral</td>
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</tr>
</tbody>
</table>

**B. Other Direct Costs**

Trainee Travel

Training Related Expenses

Total Direct Costs from R&R Budget Form (if applicable)

Consortium Training Costs (if applicable)

**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>
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<tr>
<td>2</td>
<td></td>
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</tr>
</tbody>
</table>

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

**F. Budget Justification**

Budget justification is required and must cover all budget periods.
# PHS 398 Training Budget, Cumulative Budget

**A. Stipends, Tuition/Fees**

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

<table>
<thead>
<tr>
<th>Attach Training Subaward Budget</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>30</td>
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</tr>
</tbody>
</table>

The sum of all training subaward budget forms (e.g., those attached separately on this form and those provided as part of the budget justification), must be included in the Consortium Training Costs field in the Other Direct Costs (Section B) of the PHS 398 Training Budget form.

If submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section F of the PHS 398 Training Budget form.
PHS Additional Indirect Costs - Budget Period 1

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

Add up to 4 indirect cost rates. You can combine costs associated with multiple subaward organizations in the same entry if the same indirect cost rate applies.

**Total Indirect Costs**

**Budget Justification**

(Only attach one file.)

The Budget Justification should explain what is included in the included indirect cost information.
### PHS Additional Indirect Costs - Cumulative Budget

**Totals ($)**

- **Indirect Costs**

  System calculated.
## 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.

### COST CLASSIFICATION

<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>
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</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>
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<tr>
<td>7. Site work</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>8. Demolition and removal</td>
<td></td>
<td></td>
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<tr>
<td>9. Construction</td>
<td></td>
<td></td>
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<tr>
<td>10. Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Miscellaneous</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>12. SUBTOTAL (sum of lines 1-11)</td>
<td></td>
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<tr>
<td>13. Contingencies</td>
<td></td>
<td></td>
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<tr>
<td>14. SUBTOTAL</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>15. Project (program) income</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16. TOTAL PROJECT COSTS (subtract #15 from #14)</td>
<td></td>
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</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 % $
## Introduction

1. **Introduction to Application**  
   (for Resubmission and Revision applications)  
   - Limited to 1 page (except R25 Resubmission can be 3 pages).  
   - Required for Resubmission and Revision applications.

## Research Plan Section

2. **Specific Aims**  
   - Required (except DP1, DP2, DP4, R35, R50 and X02). Limited to 1 page.

3. **Research Strategy**  
   - Adhere to page limits specified in Application Guide and/or FOA.  
   - Typically 6 or 12 pages; a small number of FOAs will specify 30 pages.

4. **Progress Report Publication List**  
   - Only allowed for Renewals and Resubmissions of renewals.

## Other Research Plan Section

5. **Vertebrate Animals**  
   - Required for all apps. (except S10), if Vertebrate Animals is Yes on the Other Project Information form.

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

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

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

9. **Letters of Support**  
   - Required for R36 applications.

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

11. **Authentication of Key Biological and/or Chemical Resources**  
    - Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.

## Appendix

12. **Appendix**  
    - Add Attachments  
    - Delete Attachments  
    - View Attachments

---

**DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the FOA as allowed or required.**

Allows for up to 10 appendices. See Application Guide and announcement for restrictions.

Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.
# PHS 398 Career Development Award Supplemental Form

## Introduction

1. **Introduction to Application**  
   (for Resubmission and Revision applications)  
   Required for Resubmission and Revision applications. Must not be included for New or Renewal applications. Limited to 1 page.

## Candidate Section

2. **Candidate Information and Goals for Career Development**  
   Required. This attachment and the Research Strategy attachment are limited to a combined total of 12 pages unless otherwise stated in the announcement.

## Research Plan Section

3. **Specific Aims**  
   Required. Limited to 1 page.

   This attachment and the Candidate Information and Goals for Career Development attachment are limited to a combined total of 12 pages unless otherwise stated in the announcement.

## Other Candidate Information Section

7. **Candidate's Plan to Provide Mentoring**  
   Required for K05 and K24. Do not include for K01, K07, K08, K18, K22, K23, K25, K76, K99, K99/R00. Limited to 6 pages.

## Mentor, Co-Mentor, Consultant, Collaborators Section

8. **Plans and Statements of Mentor and Co-Mentor(s)**  
   Required for K01, K08, K18, K23, K25, K76, K99, K99/R00. Warning if not included for K07 or K22. Limited to 6 pages.

9. **Letters of Support from Collaborators, Contributors, and Consultants**  
   Limited to 6 pages.

## Environment and Institutional Commitment to Candidate Section

10. **Description of Institutional Environment**  
    Required. Limited to 1 page.

11. **Institutional Commitment to Candidate's Research Career Development**  
    Required. Limited to 1 page.

12. **Description of Candidate's Contribution to Program Goals**  
    Required for diversity-related funding opportunity announcements only.

## Other Research Plan Sections

13. **Vertebrate Animals**  
    Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.

14. **Select Agent Research**

15. **Consortium/Contractual Arrangements**

16. **Resource Sharing**

17. **Authentication of Key Biological and/or Chemical Resources**  
    Required if project involves key biological and/or chemical resources. No system validation enforcement.
**Citizenship**

18. Appendix

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.

**19. U.S. Citizen or Non-Citizen National?**

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: □

If no, you must select the single, most appropriate Non-U.S. Citizen option.

- [ ] Yes
- [ ] No

Not allowed for K43.

Not allowed for K43.

With a Permanent U.S. Resident Visa

With a Temporary U.S. Visa

Non-U.S. Citizen national with temporary U.S. Visa is not typically a valid option, though it may be accepted for K99/R00 applications.

Not Residing in the U.S.
# Introduction

1. Introduction to Application  
   (for Resubmission and Revision applications)  
   - Required for Resubmission applications; limited to 3 pages.  
   - Required for Revision applications; limited to 1 page.

# Training Program Section

2. * Program Plan  
   - Required. Limited to 25 pages.

3. Plan for Instruction in the Responsible Conduct of Research  
   - Required. Limited to 3 pages.

4. Plan for Instruction in Methods for Enhancing Reproducibility  
   - Required for institutional career development (K12, KL2, KM1) applications and institutional training (D43, Ts).

5. Multiple PD/PI Leadership Plan  
   (if applicable)  
   - Required when multiple SrKey entries with the role of PD/PI are included on the R&R SrKey Person form.

6. Progress Report (for Renewal applications)  
   - Required for Renewal applications.

# Faculty, Trainees and Training Record Section

7. Participating Faculty Biosketches  
   - Warning if not included.

8. Letters of Support

9. Data Tables  
   - Warning if not included. User defined bookmarks in this attachment are included with the bookmarks in the submitted application image in eRA Commons.

# Other Training Program Section

10. Vertebrate Animals  
    - Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.

11. Select Agent Research

12. Consortium/Contractual Arrangements

# 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 FOA as allowed or required.

Allows for up to 10 appendices. See Application Guide and announcement for restrictions.

Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.
## Introduction

1. Introduction to Application (for Resubmission applications)

   **Required for Resubmission applications. Limited to 1 page.**

## Fellowship Applicant Section

2. * Applicant's Background and Goals for Fellowship Training

   **Required. Limited to 6 pages.**

## Research Training Plan Section

3. * Specific Aims

   **Required. Limited to 1 page.**

4. * Research Strategy

   **Required. Limited to 6 pages.**

5. * Respective Contributions

   **Required. Limited to 6 pages.**

6. * Selection of Sponsor and Institution

   **Required. Limited to 1 page.**

7. Progress Report Publication List (for Renewal applications)

   **Add Attachment**

8. * Training in the Responsible Conduct of Research

   **Required. Limited to 1 page.**

## Sponsor(s), Collaborator(s), and Consultant(s) Section

9. Sponsor and Co-Sponsor Statements

   **Required. Limited to 6 pages.**

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

    **Limited to 6 pages.**

## Institutional Environment and Commitment to Training Section

11. Description of Institutional Environment and Commitment to Training

    **Required for F05, F30, F31, F32, F33, F37, F38, F12, F99/K00. Limited to 2 pages.**

    **Includes Additional Education Information for F30 and F31 applications.**

12. Description of Candidate's Contribution to Program Goals

    **Required for diversity-related funding opportunity announcements only.**

## 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

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

   If "Yes" to euthanasia

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

   - [ ] Yes
   - [ ] No

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

   **Up to 1000 characters.**

14. Vertebrate Animals

    **Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.**
PHS Fellowship Supplemental Form

Other Research Training Plan Information

15. Select Agent Research

16. Resource Sharing Plan

17. Authentication of Key Biological and/or Chemical Resources

Rigor & transparency changes for individual fellowship applications delayed (NOT-OD-16-034). Until further notice, do not use this attachment unless specifically indicated in your funding opportunity announcement.

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):

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Add up to 200 cell lines.

19. Alternate Phone Number:

20. Degree Sought During Proposed Award:

Degree: ☐ If "other", indicate degree type:

Expected Completion Date (MM/YYYY):

21. * Field of Training for Current Proposal:

Enter appropriate 3-digit code from drop-down list.

22. * Current or Prior Kirschstein-NRSA Support?

☐ Yes ☐ No

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

* Level * Type Start Date (if known) End Date (if known) Grant Number (if known)

At least one entry is required if 'Current Or Prior Kirschstein-NRSA Support' is Yes. Can provide up to 4 support items.

23. * Applications for Concurrent Support

☐ Yes ☐ No

If yes, describe in an attached file:

Limited to 1 page. Answer must be No for F05.

24. * Citizenship:

U.S. Citizen ☐ U.S. Citizen or Non-Citizen National? ☐

Non-U.S. Citizen ☐

With a Permanent U.S. Resident Visa

With a Temporary U.S. Visa

Non-U.S. Citizen with temporary U.S. Visa only required for F05.

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

☐ Required if 'Change of Sponsoring Institution' box is checked.
### Budget Section

**All Fellowship Applicants:**

26. * Tuition and Fees:  
   - None Requested  
   - Funds Requested: 

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount</th>
<th>Academic Period</th>
<th>Number of Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Year 2</td>
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<td>Year 3</td>
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<td>Year 4</td>
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<tr>
<td>Year 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 6 (when applicable)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Funds Requested:**

### Senior Fellowship Applicants Only:

**Fields in this section are required for F33.**

27. Present Institutional Base Salary:  
   - Amount  
   - Academic Period  
   - Number of Months

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

   a. Federal Stipend Requested:  
      - Amount  
      - Number of Months

   b. Supplementation from Other Sources:  
      - Amount  
      - Number of Months  
      - Type (e.g., sabbatical leave, salary)  
      - Source

To request Childcare Costs for first year enter Amount = $2500, Months = 12, Type = 'Childcare Costs', and Source = 'NIH'. For additional years, provide 'Other Attachment' called 'Childcare_Cost_Request.pdf' on the R&R Other Project Information form specifying requested amount and number of years requested ([NOT-OD-21-074](#)).

### Appendix

29. Appendix  

**DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the FOA as allowed or required.**

Allows for up to 10 appendices. See Application Guide and announcement for restrictions.

Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.
**SBIR/STTR Information**

* Agency to which you are applying (select only one):
  - [ ] DOE
  - [ ] HHS
  - [ ] USDA
  - [ ] Other: Check HHS for all NIH, CDC, and FDA submissions.

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

* Program Type (select only one): Must select SBIR or STTR (not Both).
  - [ ] 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.)

* Agency Topic/Subtopic: Optional.

---

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

1. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement? [ ] Yes [ ] No

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

3. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? [ ] Yes [ ] No

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

5. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? [ ] If yes, insert the names of the Federal laboratories/agencies:

6. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov [ ] Yes [ ] No

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

8. 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

9. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase IIII 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/Phase II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.
**SBIR/STTR Information**

**SBIR-Specific Questions:**
Answers only required for SBIR applications.

Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
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<td>☐</td>
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<tr>
<td>☒</td>
<td>☐</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
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<tr>
<td>☒</td>
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</tbody>
</table>

**STTR-Specific Questions:**
Answers only required for STTR applications.

Questions 10 - 12 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 - 12 blank.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
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<td>☐</td>
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<tr>
<td>☒</td>
<td>☐</td>
</tr>
</tbody>
</table>

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

(1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
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<tr>
<td>☒</td>
<td>☐</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>☒</td>
<td>☐</td>
</tr>
</tbody>
</table>

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

Enter the DUNS or DUNS+4 number of the non-profit research partner for the STTR applicant.
PHS Human Subjects and Clinical Trials Information

Use of Human Specimens and/or Data

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

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

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

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:  

If No to Human Subjects

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

If Yes to Human Subjects

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

Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.

Other Requested Information

Only provide an Other Requested Information attachment when specifically requested in the funding opportunity announcement text or application guide.

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Delayed Onset Study(ies)

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

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.

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
</tr>
</thead>
</table>

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

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

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

* Always required field

---

### Section 1 - Basic Information

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

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

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

   - Yes [ ] No [ ]

   - Answer required and system enforced.

1.3. **Exemption Number**

   - 1 2 3 4 5 6 7 8

1.4. **Clinical Trial Questionnaire**

   - **Answers to questionnaire required and system enforced.**

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

   1.4.a. Does the study involve human participants? **Yes [ ] No [ ]**
   1.4.b. Are the participants prospectively assigned to an intervention? **Yes [ ] No [ ]**
   1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? **Yes [ ] No [ ]**
   1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? **Yes [ ] No [ ]**

   - 1.4.a defaults to Yes and is not editable.

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

---

### Section 2 - Study Population Characteristics

2.1. **Conditions or Focus of Study**

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

2.2. **Eligibility Criteria**

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

2.3. **Age Limits**

   - Minimum Age [ ]
   - Maximum Age [ ]

2.3.a. **Inclusion of Individuals Across the Lifespan**

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

2.4. **Inclusion of Women and Minorities**

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

2.5. **Recruitment and Retention Plan**

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

2.6. **Recruitment Status**

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

2.7. **Study Timeline**

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

2.8. **Enrollment of First Participant**

   - Date: MM/DD/YYYY.

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

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

2.9. **Inclusion Enrollment Report(s)**

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

   - **Add Inclusion Enrollment Report**

---

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

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

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

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

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

5. Enrollment Location(s)
   

6. Comments
   
   Up to 500 characters.
<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Hispanic or Latino</td>
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<tr>
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</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0</td>
</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

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

3.3. Data and Safety Monitoring Plan

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

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

- Yes
- No

3.5. Overall Structure of the Study Team

Optional.

Section 4 - Protocol Synopsis

You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose

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

4.1.c. Interventions

Up to 20 Interventions allowed.

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

4.3. Statistical Design and Power

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

4.4. Subject Participation Duration

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

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

☐ Yes  ☐ No  

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

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

| Required and system enforced if Yes. |

4.6. Is this an applicable clinical trial under FDAAA?  

☐ Yes  ☐ No

4.7. Dissemination Plan

| Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies. |

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

| Add Attachments | Delete Attachments | View Attachments |

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.
PHS Assignment Request Form

Funding Opportunity Number: Pre-populated from announcement information.

Funding Opportunity Title: Pre-populated from announcement 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.

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

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 a review panel.

Identify scientific areas of expertise needed to review your application (optional)  
Note: Do not provide names of individuals

Expertise:  
Each entry is limited to 40 characters

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