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).

Table of Contents

<table>
<thead>
<tr>
<th>Form</th>
<th>Changes introduced in FORMS-F Application Packages</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R)</td>
<td>• Updated Expiration Date</td>
<td>3</td>
</tr>
</tbody>
</table>
| PHS 398 Cover Page Supplement                  | • Updated Expiration Date
|                                                 | • Added Human Fetal Tissue Section including question -
|                                                 |   “Does the proposed project involve human fetal tissue obtained from elective abortions?”
|                                                 |   o If Yes, two new attachments are requested
|                                                 |     1. HFT Compliance Assurance
|                                                 |     2. HFT Sample IRB Consent Form
|                                                 | • Renumbered form fields, as needed                                                   | 5    |
| R&R Other Project Information                  | • Updated Expiration Date                                                               | 7    |
| Project/Performance Site Locations(s)          | • Updated Expiration Date                                                               | 8    |
| R&R Senior/Key Person Profile (Expanded)       | • Updated Expiration Date                                                               | 9    |
| R&R Budget                                     | • Updated Expiration Date                                                               | 10   |
| R&R Subaward Budget Attachment Form            | • Updated Expiration Date                                                               | 14   |
| PHS 398 Modular Budget                         | • Updated Expiration Date                                                               | 15   |
| PHS 398 Training Budget                        | • Updated Expiration Date                                                               | 16   |
| PHS 398 Training Subaward Budget Attachment(s) | • Updated Expiration Date                                                               | 18   |
| PHS Additional Indirect Costs Form             | • Updated Expiration Date                                                               | 19   |
| SF 424C Budget Information – Construction Programs | • No changes                                                                         | 21   |
| PHS 398 Research Plan                          | • Updated Expiration Date                                                               | 22   |
| PHS 398 Career Development Award Supplemental Form | • Updated Expiration Date
|                                                 | • 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                                                   | 23   |
| PHS 398 Research Training Program Plan         | • Updated Expiration Date                                                               | 25   |
| PHS Fellowship Supplemental Form               | • Updated Expiration Date
|                                                 | • 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                                                   | 26   |
| 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  
  o Do Not Assign to Awarding Components  
  o 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](#).
**APPLICATION FOR FEDERAL ASSISTANCE**

**SF 424 (R&R)**

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 institute 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:
   - State:
   - ZIP / Postal Code:
   - Country:
   - Prefix:
   - First Name:
   - Middle Name:
   - Last Name:
   - Suffix:
   - Phone Number:
   - Fax Number:
   - Email:
   - Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations. Must be 9 or 13 digits; no letters or special characters.
   - Must provide zip+4 for all zip codes.

6. **EMPLOYER IDENTIFICATION (EIN) or (TIN):**
   - Non-US organizations use 444444444.

7. **TYPE OF APPLICANT:**
   - Please select one of the following
   - Do not use these Small Business Organization Type checkboxes. NIH/CDC/FDA use SAM data to gather this information.

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

9. **NAME OF FEDERAL AGENCY:**

10. **CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:**
   - TITLE: NIH will assign CFDA post-submission.

11. **DESCRIPTIVE TITLE OF APPLICANT’S PROJECT:**
   - If Revision (box 8), provide exact title (including punctuation and spacing) as provided for awarded grant. Limited to 200 characters.

12. **PROPOSED PROJECT:**
   - Start Date
   - Ending Date
   - Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). Use 00-000 if outside the US.

13. **CONGRESSIONAL DISTRICT OF APPLICANT**
   - See Key Dates section of announcement. Start date is an estimate; typically at least nine months after submission. Project period should not exceed what is allowed in announcement.
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: ____________________________  First Name: ____________________________  Middle Name: ____________________________  Suffix: ____________________________
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.
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 ____________________________

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

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

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

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

NIH Office of Extramural Research
FORMS-F Series (Updated Feb. 26, 2020)
### 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/](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/](http://stemcells.nih.gov/research/registry/) at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Provide up to 200 cell lines.

### 4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions?*

- [ ] Yes  
- [ ] No

If "yes" then provide the HFT Compliance Assurance

Required if Yes. Cannot be included if No.

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

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

*Inventions and Patents:  Yes  No

If "Yes" then answer the following:

*Previously Reported:  Yes  No

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.
1. Are Human Subjects Involved?

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? □ Yes □ No

If yes, check appropriate exemption number. □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8

IRB Approval Date: ____________________________

Human Subject Assurance Number: ____________________________

If Human Subjects = Yes, enter the text 'None' or the approved Federalwide Assurance (FWA) number on file with OHRP. Enter the 8-digit number only.

If multiple study records are included, enter all exemptions selected across all study records.

1.b. If YES to Clinical Trials Information form.

2. Are Vertebrate Animals Used?

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? □ Yes □ No

IACUC Approval Date: ____________________________

Animal Welfare Assurance Number: ____________________________

If Vertebrate Animals = Yes, enter the text 'None' or the Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance Number.

If the IACUC review is Pending, check the appropriate box.

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: If 4a is Yes, then 4b is required. Up to 55 characters.

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

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

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

5.a. If yes, please explain: If 5 is Yes, then 5a is required. Up to 55 characters.

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

6.a. If yes, identify countries: If 6 is Yes, then a list of countries is required in 6a. Abbreviations can be used. Up to 55 characters.


7. Project Summary/Abstract

Succinct project summary of proposed work. Typically 30 lines or less; system will give error if over 1 page. If awarded this information becomes public. Do not include proprietary or confidential information.

8. Project Narrative

Typically 2-3 sentence statement of public health relevance; system will give error if over 1 page.

9. Bibliography & References Cited

Required unless otherwise noted in opportunity. Not system enforced.

10. Facilities & Other Resources

Required unless otherwise noted in opportunity. Limited system enforcement.

11. Equipment

Required unless otherwise noted in opportunity. Limited system enforcement.

12. Other Attachments

Add Attachments  Delete Attachments  View Attachments

Only provide Other Attachments when requested in the funding opportunity announcement, notice of special interest or application guide. If provided, follow any guidance regarding attachment filenames.

Field accommodates multiple attachments.
Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

Organization Name: ____________________________

DUNS Number: ____________________________

* Street1: ____________________________________________

Street2: ____________________________________________

* City: ____________________________________________ County: ____________________________

* State: ____________________________________________ Province: ____________________________

* Country: ____________________________

* ZIP / Postal Code: ____________________________ * Project/ Performance Site Congressional District: ____________________________

Additional Location(s)

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

* Street1: ____________________________________________

Street2: ____________________________________________

* City: ____________________________________________ County: ____________________________

* State: ____________________________________________ Province: ____________________________

* Country: ____________________________

* ZIP / Postal Code: ____________________________ * Project/ Performance Site Congressional District: ____________________________

Form accommodates up to 300 sites. Use the Additional Locations attachment to include any sites over 300. See Additional Performance Site Format page at: https://grants.nih.gov/grants/forms/additional-performance-site.htm
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
<th>Last Name:</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
<td>Organization Name:</td>
<td>Division:</td>
<td></td>
</tr>
<tr>
<td>* Street1:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* City:</td>
<td>County/ Parish:</td>
<td>Province:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* State:</td>
<td></td>
<td>Country:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Zip / Postal Code:</td>
<td></td>
<td>* * Phone Number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td>Credential, e.g., agency login: ORCID iD must be associated with PD/PI eRA Commons Personal Profile of Fellowship and Career Development applications. Recommended for all.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Project Role:</td>
<td>Project Role will default to PD/PI and must remain PD/PI (do not edit - we string match).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree Type:</td>
<td>Degree Year:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td>Only provide Current &amp; Pending Support if specifically requested in FOA. May be requested later in pre-award process as Just-In-Time data.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### PROFILE - Senior/Key Person 1

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
<th>Last Name:</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
<td>Organization Name:</td>
<td>Division:</td>
<td></td>
</tr>
<tr>
<td>* Street1:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* City:</td>
<td>County/ Parish:</td>
<td>Province:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* State:</td>
<td></td>
<td>Country:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Zip / Postal Code:</td>
<td></td>
<td>* * Phone Number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td>Credential, e.g., agency login: For multiple PD/PI applications, you must use the PD/PI role and provide the eRA Commons username in the Credential field for all PD/PIs. If multiple PD/PIs are included, the Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form is required.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Project Role:</td>
<td>Other Project Role Category:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree Type:</td>
<td>Degree Year:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</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.
### RESEARCH & RELATED BUDGET - Budget Period 1

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

**Budget Period:** 1  
**Start Date:**  
**End Date:**

**Expiration Date:** 12/31/2022

**ORGANIZATIONAL DUNS:**

**Enter name of Organization:**

### A. Senior/Key Person

**Prefix**  
**First**  
**Middle**  
**Last**  
**Suffix**  
**Base Salary ($)**  
**Cal. Acad. Sum.**  
**Months**  

**Requested Salary ($)**  
**Fringe Benefits ($)**  

**Funds Requested ($)**

**Project Role:** PD/PI

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

**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.**

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

**Additional Senior Key Persons:**

**Add Attachment**  
**Delete Attachment**  
**View Attachment**

**Total Funds requested for all Senior Key Persons in the attached file**

**Total Senior/Key Person**

### B. Other Personnel

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

**Number of Personnel**  
**Project Role**

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

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

**Total Number Other Personnel**

**Total Other Personnel**

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

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

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

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

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.

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

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

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>序号</th>
<th>项目</th>
<th>资金请求（$）</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>材料和用品</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>出版成本</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>咨询服务</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>ADP/计算机服务</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>子项目/联盟/合同成本</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>设备或设施租赁/用户费用</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>结构改造和翻新</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>例子可能的用途：学费减免；技术援助；病人护理费用</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>如果计划使用人类胎儿组织来自流产的，你必须包括一个“人类胎儿组织费用”项目（如果没有发生费用，输入0）。输入字符串作为要求（不带引号）。系统将只匹配字符串的字母和空格。该行项目不能与任何“其他”项目结合。</td>
<td></td>
</tr>
</tbody>
</table>

### G. 直接成本

<table>
<thead>
<tr>
<th>序号</th>
<th>总计直接成本（A至F)</th>
<th>资金请求（$）</th>
</tr>
</thead>
</table>

### H. 间接成本

<table>
<thead>
<tr>
<th>间接成本类型</th>
<th>间接成本率 (%)</th>
<th>间接成本基数（$）</th>
<th>资金请求（$）</th>
</tr>
</thead>
</table>

|总计间接成本 |  |

### I. 总直接和间接成本

<table>
<thead>
<tr>
<th>总计直接和间接机构成本（G + H）</th>
<th>资金请求（$）</th>
</tr>
</thead>
</table>

### J. 费用

<table>
<thead>
<tr>
<th>费用</th>
<th>资金请求（$）</th>
</tr>
</thead>
</table>

### K. 总成本和费用

<table>
<thead>
<tr>
<th>总计成本和费用（I + J）</th>
<th>资金请求（$）</th>
</tr>
</thead>
</table>

### L. 预算说明

(只允许附一个文件) 

预算说明是必需的，并且必须涵盖所有预算周期。
## Section A, Senior/Key Person

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

## Section B, Other Personnel

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

## Section C, Equipment

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

## Section D, Travel

1. Domestic
2. Foreign

## Section E, Participant/Trainee Support Costs

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

## Section F, Other Direct Costs

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8. Other 1
9. Other 2
10. Other 3

## Section G, Direct Costs (A thru F)

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

## Section H, Indirect Costs

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

## Section I, Total Direct and Indirect Costs (G + H)

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

## Section J, Fee

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

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

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

---

**RESEARCH & RELATED BUDGET - Cumulative Budget**

Cumulative Budget is system generated based on budget period data provided.

---

**NIH Office of Extramural Research**

FORMS-F Series (Updated Feb. 26, 2020)
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.

Click here to extract the R&R Subaward Budget Attachment

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 sum of all subaward budgets (e.g., those attached separately on this form and those provided as part of the budget justification), must be included in Line F.5 Subawards/Consortium/Contractual Costs of the parent budget.

If submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section K of the R&R Budget form. This form should only be used in conjunction with the R&R Budget form.

Do not include the Subaward Budget Attachment form with applications that use the PHS 398 Modular Budget form.
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.

### A. Direct Costs

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

<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>0.00</td>
<td></td>
<td>0.00</td>
</tr>
</tbody>
</table>

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

### B. Indirect (F&A) Costs

Form allows for up to four F&A entries.

<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>

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

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
- Consortium Justification
- Additional Narrative Justification

Add Attachment  Delete Attachment  View Attachment

Add Attachment  Delete Attachment  View Attachment

Add Attachment  Delete Attachment  View 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><strong>Undergraduate:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Term</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Predoctoral:</strong></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></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Postdoctoral:</strong></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></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Postdoctoral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other:</strong></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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number Per Stipend Level:</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stipends + Tuition/Fees Requested</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. Other Direct Costs

<table>
<thead>
<tr>
<th>Trainee Travel</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<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. 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>
<tr>
<td><strong>Total Indirect (F&amp;A) Costs Requested</strong></td>
<td></td>
<td></td>
<td></td>
</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.
## 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>
<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><strong>Total Predoctoral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Predoctoral:</strong></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><strong>Total Postdoctoral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other:</strong></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>
</tbody>
</table>

*Total Stipends + Tuition/Fees Requested*

## 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><strong>Total Direct Costs from R&amp;R Budget Form</strong> (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Consortium Training Costs (if applicable)</td>
<td></td>
</tr>
</tbody>
</table>

*Total Other Direct Costs Requested*

## 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 1</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attach Training Subaward Budget 2</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 3</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 4</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 5</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 6</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 7</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 8</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 9</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</tr>
<tr>
<td>Attach Training Subaward Budget 10</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
<td>View Attachment</td>
</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.
Optional form in Overall component of multi-project applications only. Used to gather additional indirect cost information needed from the applicant organization to correctly calculate an application's indirect costs when entire components are led by collaborating organizations.

PHS Additional Indirect Costs - Budget Period 1

<table>
<thead>
<tr>
<th>ORGANIZATIONAL DUNS:</th>
<th>Enter name of Organization:</th>
</tr>
</thead>
</table>

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

**Budget Period:** 1  * 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>
</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.
<table>
<thead>
<tr>
<th>Indirect Costs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Totals ($)</strong></td>
<td>System calculated.</td>
</tr>
</tbody>
</table>

**PHS Additional Indirect Costs - Cumulative Budget**

FORMS-F Series (Updated Feb. 26, 2020)
### 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 $ |

Be sure to include the multiplier or the total will calculate to zero.
## 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

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

8. Consortium/Contractual Arrangements

9. Letters of Support  
   - Required for R36 applications.

10. Resource Sharing Plan(s)

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

## Appendix

12. Appendix

---

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

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

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

**Introduction**

1. **Introduction to Application**
   
   **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.**

4. **Research Strategy**

   **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**

5. **Progress Report Publication List**

   (for Renewal applications)

6. **Training in the Responsible Conduct of Research**

   **Required. Limited to 1 page.**

**Mentor, Co-Mentor, Consultant, Collaborators 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.**

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**

   **Must be completed by by career applicants to diversity-related funding opportunity announcements (K01 and K22), not required for others.**

**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.**
Appendix

18. Appendix

* Citizenship

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

Yes  No

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

- [ ] Not allowed for K43.
- [ ] Not allowed for K43.

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:  

[ ]
# PHS 398 Research Training Program Plan

### 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 Sr/Key entries with the role of PD/PI are included on the R&R Sr/Key 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.
## PHS Fellowship Supplemental Form

### Introduction

1. Introduction to Application (for Resubmission applications)  
   - Required for Resubmission applications. Limited to 1 page.
   - Add Attachment  Delete Attachment  View Attachment

### Fellowship Applicant Section

2. * Applicant's Background and Goals for Fellowship Training
   - Required. Limited to 6 pages.
   - Add Attachment  Delete Attachment  View Attachment

### Research Training Plan Section

3. * Specific Aims
   - Required. Limited to 1 page.
   - Add Attachment  Delete Attachment  View Attachment

4. * Research Strategy
   - Required. Limited to 6 pages.
   - Add Attachment  Delete Attachment  View Attachment

5. * Respective Contributions
   - Required. Limited to 6 pages.
   - Add Attachment  Delete Attachment  View Attachment

6. * Selection of Sponsor and Institution
   - Required. Limited to 1 page.
   - 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
   - Required. Limited to 1 page.
   - Add Attachment  Delete Attachment  View Attachment

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

9. Sponsor and Co-Sponsor Statements
   - Required. Limited to 6 pages.
   - Add Attachment  Delete Attachment  View Attachment

10. Letters of Support from Collaborators, Contributors, and Consultants
    - Limited to 6 pages.
    - Add Attachment  Delete Attachment  View Attachment

### 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.
    - Add Attachment  Delete Attachment  View Attachment

12. Description of Candidate’s Contribution to Program Goals
    - Must be completed by candidates for diversity-related fellowships, not required for others.
    - Add Attachment  Delete Attachment  View 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
   
   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.
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/](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/](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):

Reset Entry

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)

Reset Entry

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?  

☑ Yes  ☐ No

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.

Applicants must meet citizenship requirements at time of award (not time of application submission.)

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.
# PHS Fellowship Supplemental Form

## 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>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<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:**

<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:**

**a. Federal Stipend Requested:**

- Amount
- Number of Months

**b. Supplementation from Other Sources:**

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

## Appendix

29. **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.**
### 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):**
- [ ] SBIR
- [ ] STTR
- [ ] Both (See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)

**Application Type (select only one):**
- [ ] Phase I
- [ ] Phase II
- [ ] Fast-Track
- [ ] Direct Phase II
- [ ] Phase IIA
- [ ] Phase IIB
- [ ] Phase IIC
- [ ] Commercialization Readiness Program (See agency-specific instructions to determine application type participation.)

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

**Agency Topic/Subtopic:** Optional.

---

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

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Required/Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Do you certify that at the time of award your organization will meet the</td>
<td>Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).</td>
</tr>
<tr>
<td></td>
<td>eligibility criteria for a small business as defined in the funding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>opportunity announcement?</td>
<td></td>
</tr>
<tr>
<td>1b</td>
<td>Anticipated Number of personnel to be employed at your organization at</td>
<td>Required.</td>
</tr>
<tr>
<td></td>
<td>the time of award.</td>
<td></td>
</tr>
<tr>
<td>1c</td>
<td>Is your small business majority owned by venture capital operating</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>companies, hedge funds, or private equity firms?</td>
<td></td>
</tr>
<tr>
<td>1d</td>
<td>Is your small business a Faculty or Student-Owned entity?</td>
<td>Selection required.</td>
</tr>
<tr>
<td>2</td>
<td>Does this application include subcontracts with Federal laboratories or</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>any other Federal Government agencies?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If yes, insert the names of the Federal laboratories/agencies:</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Are you located in a HUBZone? To find out if your business is in a</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>HUBZone, use the mapping utility provided by the Small Business</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Administration at its web site: <a href="http://www.sba.gov">http://www.sba.gov</a></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Will all research and development on the project be performed in its</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>entirety in the United States?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* If no, provide an explanation in an attached file.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Has the applicant and/or Program Director/Principal Investigator</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>submitted proposals for essentially equivalent work under other</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Federal program solicitations or received other Federal awards for</td>
<td></td>
</tr>
<tr>
<td></td>
<td>essentially equivalent work?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* If yes, insert the names of the other Federal agencies:</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Disclosure Permission Statement: If this application does not result</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>in an award, is the Government permitted to disclose the title of your</td>
<td></td>
</tr>
<tr>
<td></td>
<td>proposed project, and the name, address, telephone number and email</td>
<td></td>
</tr>
<tr>
<td></td>
<td>address of the official signing for the applicant organization to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>state-level economic development organizations that may be interested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>in contacting you for further information (e.g., possible</td>
<td></td>
</tr>
<tr>
<td></td>
<td>collaborations, investment)?</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Commercialization Plan: The following applications require a</td>
<td>Selection required.</td>
</tr>
<tr>
<td></td>
<td>Commercialization Plan: Phase I (DOE only), Phase II (all agencies),</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phase III Fast-Track (all agencies). Include a Commercialization</td>
<td>Required if Yes. Up to 250 characters. Cannot include if No.</td>
</tr>
<tr>
<td></td>
<td>Plan in accordance with the agency announcement and/or agency-specific</td>
<td></td>
</tr>
<tr>
<td></td>
<td>instructions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Attach File:</td>
<td></td>
</tr>
</tbody>
</table>

---

NIH Office of Extramural Research

FORMS-F Series (Updated Feb. 26, 2020)

Page 29
### SBIR/STTR Information

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

* 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.

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

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

* 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?

* 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.

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:

- [ ] 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**

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

**Study Record(s)**

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

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

**Delayed Onset Study(ies)**

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

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.

**Information populated from R&R Other Project Information form.**

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

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

- [ ] Add Attachment  
- [ ] Delete Attachment  
- [ ] View Attachment
Study Record: PHS Human Subjects and Clinical Trials Information

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)
Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations?  
Yes  No

1.3. Exemption Number

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

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study
Required and system enforced unless study is exemption 4. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria
Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits
Minimum Age  Maximum Age
Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

2.3.a. Inclusion of Individuals Across the Lifespan
Required and system enforced unless study is exemption 4.

2.4. Inclusion of Women and Minorities
Required and system enforced unless study is exemption 4.

2.5. Recruitment and Retention Plan
Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.6. Recruitment Status
Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.7. Study Timeline
Required and system enforced unless study is exemption 4, 1.4.a=No, 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)

2.9. Inclusion Enrollment Report(s)
Inclusion Enrollment Reports required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

* 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>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Not Hispanic or Latino</td>
<td>Hispanic or Latino</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>More than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>0</strong></td>
<td><strong>0</strong></td>
<td><strong>0</strong></td>
<td><strong>0</strong></td>
<td><strong>0</strong></td>
</tr>
<tr>
<td>Racial Categories</td>
<td>Ethnic Categories</td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-------------------</td>
<td>-------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not Hispanic or Latino</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hispanic or Latino</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unknown/Not Reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than One Race</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Female 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unknown/Not Reported 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Report 1 of 1
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

Yes  No  N/A

Answer required and system enforced. "N/A" is only a valid option if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan

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

3.3. Data and Safety Monitoring Plan

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

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

Yes  No

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

3.5. Overall Structure of the Study Team

Optional.

Section 4 - Protocol Synopsis

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

4.1. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose

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

4.1.c. Interventions

Up to 20 Interventions allowed.

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Up to 200 characters.</td>
<td>Up to 1,000 characters.</td>
</tr>
</tbody>
</table>

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

4.1.d. Study Phase

Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and N/A

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

4.1.e. Intervention Model

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

4.1.f. Masking

Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/Outcomes Assessor check boxes.

4.1.g. Allocation

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

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

### 4.3. Statistical Design and Power

- Required and system enforced for CT study unless otherwise noted in 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 [ ]

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

- Required and system enforced if Yes.

### 4.6. Is this an applicable clinical trial under FDAAA?

- Yes [ ]
- No [ ]

### 4.7. Dissemination Plan

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

---

### Section 5 - Other Clinical Trial-related Attachments

#### 5.1. Other Clinical Trial-related Attachments

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

Funding Opportunity Number: Pre-populated from announcement information.

Funding Opportunity Title: 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: ____________________________ ____________________________ ____________________________ Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Study Section Assignment Suggestions (optional)

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

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

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

Suggested Study Sections: ____________________________ ____________________________ ____________________________ Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Rationale for assignment suggestions (optional)

Entry is limited to 1000 characters.

Up to 1000 characters.
PHS Assignment Request Form

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