Table of Contents

<table>
<thead>
<tr>
<th>Forms Common to Most Application Packages</th>
<th>Page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R)</td>
<td>2</td>
</tr>
<tr>
<td>PHS 398 Cover Page Supplement</td>
<td>4</td>
</tr>
<tr>
<td>R&amp;R Other Project Information</td>
<td>6</td>
</tr>
<tr>
<td>Project/Performance Site Location(s)</td>
<td>7</td>
</tr>
<tr>
<td>R&amp;R Senior/Key Person Profile (Expanded)</td>
<td>8</td>
</tr>
<tr>
<td>SBIR/STTR Information</td>
<td>9</td>
</tr>
<tr>
<td>PHS Human Subjects and Clinical Trials Information</td>
<td>11</td>
</tr>
<tr>
<td>PHS Assignment Request Form</td>
<td>17</td>
</tr>
<tr>
<td><strong>Budget Forms</strong></td>
<td></td>
</tr>
<tr>
<td>PHS Modular Budget</td>
<td>19</td>
</tr>
<tr>
<td>R&amp;R Budget</td>
<td>20</td>
</tr>
<tr>
<td>R&amp;R Subaward Budget Attachment(s) Form</td>
<td>24</td>
</tr>
<tr>
<td>PHS 398 Training Budget</td>
<td>25</td>
</tr>
<tr>
<td>Training Subaward Budget Attachment Form</td>
<td>27</td>
</tr>
<tr>
<td>PHS Additional Indirect Costs</td>
<td>28</td>
</tr>
<tr>
<td>Construction Budget</td>
<td>25</td>
</tr>
<tr>
<td><strong>Research Plan and Equivalent Forms</strong></td>
<td></td>
</tr>
<tr>
<td>PHS 398 Research Plan</td>
<td>30</td>
</tr>
<tr>
<td>PHS 398 Career Development Award Supplemental Form</td>
<td>31</td>
</tr>
<tr>
<td>PHS 398 Research Training Program Plan</td>
<td>33</td>
</tr>
<tr>
<td>PHS Fellowship Supplement Form</td>
<td>34</td>
</tr>
</tbody>
</table>

**NOTES:**

- The Funding Opportunity Announcement (FOA) and associated application guide remain the official documents for defining application requirements. This resource is meant to complement, not replace, those documents.
- NIH application packages include a subset of the forms included in this resource. You will only need to complete the forms provided to you with a specific FOA.
- The actual display of the forms depends on your submission method (ASSIST, system-to-system solution, Workspace). The same forms, form fields and guidance apply regardless of submission option even if the display is slightly different.
- This resource is for FORMS-E application packages, see Do I Have the Right Forms for My Application?
- Registration in multiple systems is needed prior to submission, see Get Registered! Can take 6 weeks – start early!
- Don’t forget to periodically check the Related Notices section of the FOA for any updates to instructions or policies since the opportunity was posted.
- The blue annotations throughout this resource represent tips, processing notes and eRA system business rule checks (i.e., validations).
APPLICATION FOR FEDERAL ASSISTANCE

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

2. DATE SUBMITTED
   - Applicant Identifier
   - Pre-application unless specifically noted in FQA.
   - Use Changed/Corrected when submitting again to Grants.gov to correct eRA identified errors/warnings.

3. DATE RECEIVED BY STATE

4. a. Federal Identifier
b. Agency Routing Identifier
   - State Application Identifier
   - If New (box 8), leave blank unless otherwise instructed in FOA. If Resubmission, Renewal or Revision (box 8), use institute and serial # of previous NIH grant/application # (e.g., use CA987654 from 1R01CA987654-01).

5. APPLICANT INFORMATION
   - Legal Name:
   - Department:
   - Division:
   - Street1:
   - Street2:
   - City:
   - County / Parish:
   - Province:
   - State:
   - Country: USA: UNITED STATES
   - ZIP / Postal Code:
   - Phone Number:
   - Fax Number:
   - Email:
   - Person to be contacted on matters involving this application
   - Prefix:
   - First Name:
   - Middle Name:
   - Last Name:
   - Suffix:
   - Position/Title:

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

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

8. TYPE OF APPLICATION:
   - See application guide for definitions.
   - 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:

11. DESCRIPTIVE TITLE OF APPLICANT’S PROJECT:

12. PROPOSED PROJECT:

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

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: [ ]

Last Name: [ ]

Suffix: [ ]

Position/Title: [ ]

Organization Name: [ ]

Department: [ ]

Division: [ ]

Street1: [ ]

Street2: [ ]

City: [ ]

County / Parish: [ ]

State: [ ]

ZIP / Postal Code: [ ]

Country: [ ]

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 [ ]

b. NO [ ]

I agree [ ]


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

Add Attachment
Delete Attachment
View Attachment

19. Authorized Representative

Prefix: [ ]

First Name: [ ]

Middle Name: [ ]

Last Name: [ ]

Suffix: [ ]

Position/Title: [ ]

Organization: [ ]

Department: [ ]

Division: [ ]

Street1: [ ]

Street2: [ ]

City: [ ]

County / Parish: [ ]

State: [ ]

Province: [ ]

ZIP / Postal Code: [ ]

Country: [ ]

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 [ ]

21. Cover Letter Attachment [ ]

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. Do not include assignment or review request information in your cover letter (use PHS Assignment Request Form for assignment and review information instead).
# PHS 398 Cover Page Supplement

## 1. Vertebrate Animals Section

<table>
<thead>
<tr>
<th>Are vertebrate animals euthanized?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If **Yes** to euthanasia

<table>
<thead>
<tr>
<th>Is method consistent with American Veterinary Medical Association (AVMA) guidelines?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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

**Up to 1000 characters.**

## 2. *Program Income Section*

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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?*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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:

<table>
<thead>
<tr>
<th>Specific stem cell line cannot be referenced at this time. One from the registry will be used.</th>
</tr>
</thead>
</table>

**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. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents:*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If **Yes** then answer the following:

*Previously Reported:*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

**Updated: March 8, 2018**

**FORMS-E Series**

**Page 4 of 36**
5. Change of Investigator/Change of Institution Section

☐ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix: 
*First Name: 
Middle Name: 
*Last Name: 
Suffix: 

☐ Change of Grantee Institution

*Name of former institution:
1. Are Human Subjects Involved?
   - If YES to Human Subjects
     - Is the Project Exempt from Federal regulations?  
       - [ ] Yes  
       - [ ] No
     - If yes, check appropriate exemption number.
       - [ ] 1  
       - [ ] 2  
       - [ ] 3  
       - [ ] 4  
       - [ ] 5  
       - [ ] 6  
       - [ ] 7  
       - [ ] 8
     - If no, is the IRB review Pending?  
       - [ ] Yes  
       - [ ] No
     - IRB Approval Date: [ ]
     - Human Subject Assurance Number: [ ]

2. Are Vertebrate Animals Used?
   - If YES to Vertebrate Animals
     - Is the IACUC review Pending?  
       - [ ] Yes  
       - [ ] No
     - IACUC Approval Date: [ ]
     - Animal Welfare Assurance Number: [ ]

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

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

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

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

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. Not system enforced.

11. Equipment
    - Required unless otherwise noted in opportunity. Not system enforced.

12. Other Attachments
    - Only provide Other Attachments when requested in the funding opportunity announcement text or application guide. Field accommodates multiple attachments.
Project/Performance Site Location(s)

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

Organization Name:
DUNS Number:

* Street1:
Street2:
* City:
* State:
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code:

* Project/ Performance Site Congressional District:

Additional Location(s)

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

#### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Field</th>
<th>Information Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix:</td>
<td>First Name:</td>
</tr>
<tr>
<td>* Last Name:</td>
<td>Middle Name:</td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
</tr>
<tr>
<td>Street1:</td>
<td></td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>County/Parish:</td>
<td></td>
</tr>
<tr>
<td>State:</td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td></td>
</tr>
<tr>
<td>Credential, e.g., agency login:</td>
<td></td>
</tr>
<tr>
<td>* Project Role:</td>
<td>PD/PI</td>
</tr>
<tr>
<td>Other Project Role Category:</td>
<td></td>
</tr>
<tr>
<td>Degree Type:</td>
<td></td>
</tr>
<tr>
<td>Degree Year:</td>
<td></td>
</tr>
<tr>
<td>* Attach Biographical Sketch</td>
<td></td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td></td>
</tr>
</tbody>
</table>

**VALID ERA 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).

#### PROFILE - Senior/Key Person 1

<table>
<thead>
<tr>
<th>Field</th>
<th>Information Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix:</td>
<td>First Name:</td>
</tr>
<tr>
<td>* Last Name:</td>
<td>Middle Name:</td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
</tr>
<tr>
<td>Street1:</td>
<td></td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>Countyst:</td>
<td></td>
</tr>
<tr>
<td>State:</td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td></td>
</tr>
<tr>
<td>Credential, e.g., agency login:</td>
<td></td>
</tr>
<tr>
<td>* Project Role:</td>
<td></td>
</tr>
<tr>
<td>Other Project Role Category:</td>
<td></td>
</tr>
<tr>
<td>Degree Type:</td>
<td></td>
</tr>
<tr>
<td>Degree Year:</td>
<td></td>
</tr>
<tr>
<td>* Attach Biographical Sketch</td>
<td></td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td></td>
</tr>
</tbody>
</table>

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.

---

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.

Updated: March 8, 2018

FORMS-E Series

Page 8 of 36
**SBIR/STTR Information**

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

- **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 application type participation.)

- **Application Type (select only one):**
  - [ ] Phase I
  - [ ] Phase II
  - [ ] Fast-Track
  - [ ] Direct Phase II
  - [ ] Phase IIA
  - [ ] Phase IIB

- **Commercialization Readiness Program** (See agency-specific instructions to determine application type participation.)
  - Congressional authority to accept CRP expired.

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

  - **1a.** Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement? **Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).**

  - **1b.** Anticipated Number of personnel to be employed at your organization at the time of award. **Required.**

  - **1c.** Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? **Selection required.**

  - **1d.** Is your small business a Faculty or Student-Owned entity? **Selection required.**

  - **2.** Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? **Selection required.**

    - If yes, insert the names of the Federal laboratories/agencies:

    - Required if Yes. Up to 250 characters. Cannot include if No.

  - **3.** Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov **Selection required.**

  - **4.** Will all research and development on the project be performed in its entirety in the United States? **Selection required.**

    - If no, provide an explanation in an attached file.

    - Required if No. Cannot include if Yes.

  - **5.** Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? **Selection required.**

    - If yes, insert the names of the other Federal agencies:

    - Required if Yes. Up to 250 characters. Cannot include if No.

  - **6.** Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? **Selection required.**

  - **7.** Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase I/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. **Required for Phase II, Direct Phase II, Phase IIB, Phase IIA/Phase IIB Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.**

* Add Attachment | Delete Attachment | View Attachment

Updated: March 8, 2018  FORMS-E Series  Page 9 of 36
### 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.

* 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?

#### 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.
Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

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

Does the proposed research involve human specimens and/or data? □ Yes □ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Required if Yes to human specimens/data question.

Answer required and system enforced when human subjects is No.

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 the study name and a justification for omission of human subjects study information.

Other Requested Information

Check Application Guide and opportunity instructions to determine if attachment is needed.

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.

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>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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

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 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] 8
If Study Exempt is Yes, must provide exemption number.

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

1.5. 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 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 [ ] Dropout[ ] Years [ ] Months Maximum Age [ ] Dropout[ ] Years [ ] Months

2.4. Inclusion of Women, Minorities, and Children
Required and system enforced unless study is exemption 4. 1.4.a=No, or otherwise noted in opportunity.

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
Not yet recruiting. Recruiting by invitation. Active, not recruiting. Completed. Suspended. Terminated (Halted Prematurely). Withdrawn (No Participants Enrolled). If "N/A (No Limit)" selected, do not provide numerical min/ max age.

2.7. Study Timeline

2.8. Enrollment of First Subject
Inclusion Enrollment Report(s)

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

Updated: March 8, 2018
FORMS-E Series Page 12 of 36

* 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. Such studies must include HS information, but will receive a system error if information is included in CT study fields in sections 4 or 5 of form.
### Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource
   - Yes
   - No
   - Answer required and system enforced.

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

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

4. Enrollment Location(s)

5. Comments
   - Up to 500 characters.

**Planned**
- Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

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

Updated: March 8, 2018
<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Unknown/Not Reported Ethnicity</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Unknown/Not Reported</td>
<td>Female</td>
</tr>
<tr>
<td>American Indian/Alaska Native</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>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</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>
</tr>
<tr>
<td>White</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>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

Add Attachment  Delete Attachment  View Attachment

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 for fellowship, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan

Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies.

Add Attachment  Delete Attachment  View Attachment

3.3. Data and Safety Monitoring Plan

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

Add Attachment  Delete Attachment  View Attachment

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.

Add Attachment  Delete Attachment  View Attachment

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. Brief Summary

Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.2. Study Design

All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

4.2.a. Narrative Study Description

Up to 32,000 characters.

4.2.b. Primary Purpose

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

4.2.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)

4.2.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 Other

Is this an NIH-defined Phase III clinical trial?

Yes  No

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

4.2.e. Intervention Model

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

4.2.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.
4.2.g. Allocation

Dropdown list: N/A, Randomized; and Non-randomized

Non-randomized

4.3. Outcome Measures

At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

<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. Other</td>
</tr>
<tr>
<td>Brief Description</td>
<td>Up to 999 characters.</td>
</tr>
</tbody>
</table>

4.4. Statistical Design and Power

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

4.5. Subject Participation Duration

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

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

☐ Yes  ☐ No

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

4.6.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.

4.7. 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.
Optional form in most grant application packages.

PHS Assignment Request Form

The PHS Assignment Request Form will be 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.

Funding Opportunity Number: Pre-populated from announcement information.

Funding Opportunity Title: Pre-populated from announcement information.

Awarding Component Assignment Request (optional)

If you have a preference for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation and enter it below. All requests will be considered; however, assignment requests cannot always be honored.

Awarding Components: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

<table>
<thead>
<tr>
<th>Assign to Awarding Component</th>
<th>First Choice</th>
<th>Second Choice</th>
<th>Third Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Assign to Awarding Component</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Study Section Assignment Request (optional)

If you have a preference for study section assignment, use the link below to identify the appropriate study section (e.g., NIH Scientific Review Group or Special Emphasis Panel) and enter it below. Remove all hyphens, parentheses, and spaces. All requests will be considered; however, assignment requests cannot always be honored.

Study Sections: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

<table>
<thead>
<tr>
<th>Assign to Study Section</th>
<th>First Choice</th>
<th>Second Choice</th>
<th>Third Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Assign to Study Section</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Only 20 characters allowed
List individuals who should not review your application and why (optional)  
Only 1000 characters allowed

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

Expertise:  
Only 40 characters allowed
## A. Direct Costs

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

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>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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)

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

## Cumulative Budget Information

### 1. Total Costs, Entire Project Period

- Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period $ 0.00
- Section A, Total Consortium Indirect (F&A) for Entire Project Period
- 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
**RESEARCH & RELATED BUDGET - Budget Period 1**

**ORGANIZATIONAL DUNS:**

**Enter name of Organization:**

**Budget Type:**

- Project
- Subaward/Consortium

**Budget Period:**

- Start Date: 
- End Date: 

**OMB Number:** 4040-0001

**Expiration Date:** 10/31/2019

**A. Senior/Key Person**

Only the primary applicant organization should use Budget Type of Project. Every Sr/Key listed must have measurable effort in either Calendar Months or a combination of Academic and Summer Months.

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

<table>
<thead>
<tr>
<th>Role</th>
<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></td>
<td>Post Doctoral Associates</td>
<td>Cal.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Graduate Students</td>
<td>Cal.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Undergraduate Students</td>
<td>Cal.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Secretarial/Clerical</td>
<td>Cal.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Additional Senior Key Persons:

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.

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)**

Updated: March 8, 2018

FORMS-E Series

Page 20 of 36
### 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:**

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

<table>
<thead>
<tr>
<th>Total funds requested for all equipment listed in the attached file</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Equipment**

### D. Travel

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

2. Foreign Travel Costs

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

### E. Participant/Trainee Support Costs

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

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant/Trainee Support Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>F. Other Direct Costs</td>
<td>Funds Requested ($)</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------</td>
</tr>
<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.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td></td>
</tr>
<tr>
<td>Total Other Direct Costs</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>H. Indirect Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect Cost Type</td>
<td>Indirect Cost Rate (%)</td>
</tr>
<tr>
<td>Cognizant Federal Agency</td>
<td></td>
</tr>
<tr>
<td>(Agency Name, POC Name, and POC Phone Number)</td>
<td></td>
</tr>
<tr>
<td>Total Indirect Costs</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>L. Budget Justification</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Only attach one file.)</td>
<td>Budget Justification is required and must cover all budget periods.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## RESEARCH & RELATED BUDGET - Cumulative Budget

<table>
<thead>
<tr>
<th>Section A, Senior/Key Person</th>
<th>Totals ($)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Section B, Other Personnel</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
</tbody>
</table>

| Section C, Equipment        | Totals ($) |

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

<table>
<thead>
<tr>
<th>Section E, Participant/Trainee Support Costs</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td></td>
</tr>
<tr>
<td>2. Stipends</td>
<td></td>
</tr>
<tr>
<td>3. Travel</td>
<td></td>
</tr>
<tr>
<td>4. Subsistence</td>
<td></td>
</tr>
<tr>
<td>5. Other</td>
<td></td>
</tr>
<tr>
<td>6. Number of Participants/Trainees</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section F, Other Direct Costs</th>
<th>Totals ($)</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. Other 1</td>
<td></td>
</tr>
<tr>
<td>9. Other 2</td>
<td></td>
</tr>
<tr>
<td>10. Other 3</td>
<td></td>
</tr>
</tbody>
</table>

| Section G, Direct Costs (A thru F) | Totals ($) |

| Section H, Indirect Costs        | Totals ($) |

| Section I, Total Direct and Indirect Costs (G + H) | Totals ($) |

| Section J, Fee                     | Totals ($) |

| Section K, Total Costs and Fee (I + J) | Totals ($) |

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

---

**Section B, Other Personnel**

- Total Number Other Personnel: [Blank]

**Section C, Equipment**

- [Blank]

**Section D, Travel**

1. Domestic: [Blank]
2. Foreign: [Blank]

**Section E, Participant/Trainee Support Costs**

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

**Section F, Other Direct Costs**

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

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

- [Blank]

**Section H, Indirect Costs**

- [Blank]

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

- [Blank]

**Section J, Fee**

- [Blank]

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

- [Blank]
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 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.
### A. Stipends, Tuition/Fees

<table>
<thead>
<tr>
<th>Number of Trainees</th>
<th>Full Time</th>
<th>Short Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undergraduate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number Per Stipend Level:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-Year/Soph.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Predoctoral:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dual Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Predoctoral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postdoctoral:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-degree Seeking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree Seeking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Postdoctoral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number Per Stipend Level:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Stipends + Tuition/Fees Requested</td>
<td></td>
<td></td>
</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>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Indirect Cost Rate must be 8 for all Ts.**

### 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></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><strong>Total Predoctoral</strong></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><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>

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>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>
</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.

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

**ORGANIZATIONAL DUNS:** [ ]

**Enter name of Organization:** [ ]

**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>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</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.) [ ]

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

The Budget Justification should explain what is included in the included indirect cost information.
<table>
<thead>
<tr>
<th>Indirect Costs</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>System calculated.</td>
</tr>
</tbody>
</table>
**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

**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

**Notes**

- 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 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.

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
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.

### Other Research Plan Sections
12. Vertebrate Animals  
    Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.

13. Select Agent Research

14. Consortium/Contractual Arrangements

15. Resource Sharing

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

17. Appendix

* Citizenship

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

[ ] Yes

[ ] No

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

[ ] Not allowed for K43.

[ ] With a Permanent U.S. Resident Visa

[ ] With a Temporary U.S. Visa

[ ] Not Residing in the U.S.

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.

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

1. Introduction to Application (for Resubmission and Revision applications)
   - 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
   - Rigor & transparency changes for training applications delayed (NOT-OD-16-034).
   - Until further notice, do not use this attachment unless specifically indicated in your funding opportunity announcement.

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.

## 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)*

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**
    - Limited to 2 pages. Includes Additional Education Information for F30 and F31 applications.

## 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

12. 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.

13. **Vertebrate Animals**
    - Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.
16. 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

17. 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.

18. Alternate Phone Number: 


19. Degree Sought During Proposed Award:

Degree: 

If "other", indicate degree type: 

Expected Completion Date (MM/YYYY): 

20. * Field of Training for Current Proposal:

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

21. * 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.

22. * Applications for Concurrent Support

☐ Yes  ☐ No

If yes, describe in an attached file: 

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

23. * Citizenship:

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

☐ Yes  ☐ No

Non-U.S. Citizen

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

With a Permanent U.S. Resident Visa  

With a Temporary U.S. Visa

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:

24. Change of Sponsoring Institution

(required if "Change of Sponsoring Institution" box is checked.

Name of Former Institution:

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

#### All Fellowship Applicants:

25. * Tuition and Fees:

<table>
<thead>
<tr>
<th>Year</th>
<th>None Requested</th>
<th>Funds Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 6 (when applicable)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Senior Fellowship Applicants Only:

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

26. Present Institutional Base Salary:

<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:

#### Stipends/Salary During First Year of Proposed Fellowship:

27. a. Federal Stipend Requested:

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

27. b. Supplementation from Other Sources:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Number of Months</th>
<th>Type (e.g., sabbatical leave, salary)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Appendix

28. 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.