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

Grant applications to NIH for due dates on/after January 25, 2023 must use application form packages with a “FORMS-H” Competition ID. See High-level Grant Application Form Change Summary: FORMS-H for a list of specific form updates.

Each funding opportunity and associated application package uses a unique subset of the application forms found in this resource. You only need to complete the forms provided to you with a specific funding opportunity.

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Notes:
- The funding opportunity, notices in the NIH Guide, and the How to Apply – 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: Register.
APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

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

2. DATE SUBMITTED
   - Applicant Identifier
   - State Application Identifier

   Do not use Pre-application unless indicated in funding opportunity.

3. DATE RECEIVED BY STATE

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).

   For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX).

   If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678).

   Unique Entity Identifier (UEI) replaced DUNS. Same identifier must be used in all registrations and within this field of application. UEIs are 12 alpha-numeric characters.

5. APPLICANT INFORMATION
   - Legal Name:
   - Department:
   - Division:
   - Street1:
   - Street2:
   - City:
   - County / Parish:
   - State:
   - Zip / Postal Code:
   - Country:
   - Phone Number:
   - Fax Number:
   - Email: Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used.

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.

   See application guide for definitions.

8. TYPE OF APPLICATION:
   - See application guide for definitions.
   - If Revision, mark appropriate box(es).

   - 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:
   - CFDA is also referred to as Assistance Listing Number (ALN). NIH will assign CFDA/ALN 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

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.

   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 funding opportunity.
15. ESTIMATED PROJECT FUNDING
Manually enter estimated project funding amounts.

a. Total Federal Funds Requested

b. Total Non-Federal Funds

c. Total Federal & Non-Federal Funds

d. Estimated Program Income

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

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

b. NO
□ PROGRAM IS NOT COVERED BY E.O. 12372; OR
□ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

   [I agree]

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

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

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

19. Authorized Representative

Prefix: ____________________________ First Name: ____________________________ Middle Name: ____________________________

Last Name: ____________________________ Suffix: ____________________________

Position/Title: ____________________________

Organization: ____________________________

Department: ____________________________ Division: ____________________________

Street1: ____________________________

Street2: ____________________________

City: ____________________________ County / Parish: ____________________________

State: ____________________________ Province: ____________________________

Country: ____________________________ 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
1. Vertebrate Animals Section

Are vertebrate animals euthanized?  

- Yes  
- No  

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

If "Yes" to euthanasia

- Is method consistent with American Veterinary Medical Association (AVMA) guidelines?  
  
- Yes  
- No  

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

2. Program Income Section

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

- Yes  
- No  

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

<table>
<thead>
<tr>
<th>*Budget Period</th>
<th>*Anticipated Amount ($)</th>
<th>*Source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<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: https://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

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

Cell Line(s) (Example: 0004):

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

4. Human Fetal Tissue Section

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

- Yes  
- No  

If "yes" then provide the HFT Compliance Assurance

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: ___________________________

Suffix: ________________________________

If change of PD/PI box is checked, you must provide the last name of the former PD/PI.

☐ 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.
DO NOT check box. NIH only accepts applications from registered organizations.

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

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:

* Street1:

Street2:

* City:

County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code:

* Project/Performance Site Congressional District:

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

Organization Name:

UEI:

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

* Street1:

Street2:

* City:

County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code:

* Project/Performance Site Congressional District:

List all performance sites, including any foreign sites. Provide a list of resources available from each site in the Facilities & Other Resources attachment on the R&R Other Project Information form. Describe any consortium/contractual arrangements in the Consortium/Contractual Arrangements attachment on the PHS 398 Research Plan form or equivalent form.

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

#### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix: * First Name:</td>
<td></td>
</tr>
<tr>
<td>Last Name:</td>
<td></td>
</tr>
<tr>
<td>Position/Title:</td>
<td></td>
</tr>
<tr>
<td>Organization Name:</td>
<td></td>
</tr>
<tr>
<td>Street1:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>State:</td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td>USA: UNITED STATES</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>Degree Type:</td>
<td></td>
</tr>
<tr>
<td>Degree Year:</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- ORCID ID must be associated with PD/PI eRA Commons Personal Profile of Fellowship and Career Development applications. Recommended for all.
- Project Role will default to PD/PI and must remain PD/PI (do not edit - we string match).
- Only provide Current & Pending Support if specifically requested in funding opportunity. May be requested later in pre-award process as Just-In-Time data.

#### PROFILE - Senior/Key Person 1

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix: * First Name:</td>
<td></td>
</tr>
<tr>
<td>Last Name:</td>
<td></td>
</tr>
<tr>
<td>Position/Title:</td>
<td></td>
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<td>Organization Name:</td>
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<td>State:</td>
<td></td>
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<tr>
<td>Country:</td>
<td>USA: UNITED STATES</td>
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<tr>
<td>Phone Number:</td>
<td></td>
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<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>Degree Type:</td>
<td></td>
</tr>
<tr>
<td>Degree Year:</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- Credentials required for all Sr/Key entries (including Other Significant Contributors) and are used to determine potential conflicts of interest. For multiple PD/PIs: use the PD/PI role, provide valid & active eRA Commons ID in the Credential field, and include a Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form.
- Only provide Current & Pending Support if specifically requested in funding opportunity. May be requested later in pre-award process as Just-In-Time data.
R&R Budget form must be used if the application requests >$250K in any budget period, is submitted by a foreign institution, or proposes the use of human fetal tissue from elective abortions.

Provide 12 alpha-numeric character Unique Entity Identifier (UEI) for the organization whose budget is reflected on this form.

**RESEARCH & RELATED BUDGET - Budget Period 1**

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

**UEI:**

**Enter name of Organization:**

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

**OMB Number:** 4040-0001  
**Expiration Date:** 11/30/2025

---

**A. Senior/Key Person**

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

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

Prefix First Middle Last  
Suffix  
**Base Salary ($):**  
**Requested Salary ($):**  
**Fringe Benefits ($):**  
**Funds Requested ($):**

Months  
Cal.  
Acad.  
Sum.

**Project Role:**  
- PD/PI

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

**Additional Senior Key Persons:**

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

Add Attachment  
Delete Attachment  
View Attachment

**B. Other Personnel**

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

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Graduate Students</td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</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 Salary, Wages and Fringe Benefits (A+B)**

---

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

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

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

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

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

<table>
<thead>
<tr>
<th>Additional Equipment:</th>
</tr>
</thead>
</table>

Total funds requested for all equipment listed in the attached file

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

### 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>
</tr>
</thead>
</table>

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

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

2. Stipends

3. Travel

4. Subsistence

5. Other

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

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. Up to 10 additional Other Direct Costs line items can be added. Examples of possible uses: Tuition Remission, Technical Assistance, and Patient Care Costs.

9. FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a "Data Management and Sharing Costs" line item covering DMS costs, including personnel costs (e.g., personnel who will be curating data for the project). If no cost incurred, enter 0. Type the string as requested (without quotation marks) and do not combine the line item with any "Other" costs.

10. If proposing the use of human fetal tissue from elective abortions, you must include a "Human Fetal Tissue Costs" item (if no cost incurred, enter 0). Type the string as requested (without quotation marks) and do not combine the line item with any "Other" costs.

G. Direct Costs

H. Indirect Costs

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

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

I. Total Direct and Indirect Costs

J. Fee

K. Total Costs and Fee

L. Budget Justification

(Only attach one file.)

Budget Justification is required and must cover all budget periods.

FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a section titled "Data Management and Sharing Justification" that provides a brief brief summary of DMS activities and justification for their costs.
<table>
<thead>
<tr>
<th>Section A, Senior/Key Person</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Section B, Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
<td></td>
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<tr>
<td>Section C, Equipment</td>
<td></td>
</tr>
<tr>
<td>Section D, Travel</td>
<td></td>
</tr>
<tr>
<td>1. Domestic</td>
<td></td>
</tr>
<tr>
<td>2. Foreign</td>
<td></td>
</tr>
<tr>
<td>Section E, Participant/Trainee Support Costs</td>
<td></td>
</tr>
<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>
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<tr>
<td>4. Subsistence</td>
<td></td>
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<tr>
<td>5. Other</td>
<td></td>
</tr>
<tr>
<td>6. Number of Participants/Trainees</td>
<td></td>
</tr>
<tr>
<td>Section F, Other Direct Costs</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>
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<td>7. Alterations and Renovations</td>
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<tr>
<td>8. Other 1</td>
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<td>9. Other 2</td>
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<td>10. Other 3</td>
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<td>11. Other 4</td>
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<td>12. Other 5</td>
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<td>13. Other 6</td>
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<tr>
<td>14. Other 7</td>
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<td>15. Other 8</td>
<td></td>
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<tr>
<td>16. Other 9</td>
<td></td>
</tr>
<tr>
<td>17. Other 10</td>
<td></td>
</tr>
<tr>
<td>Section</td>
<td>Details</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>G, Direct Costs (A thru F)</td>
<td></td>
</tr>
<tr>
<td>H, Indirect Costs</td>
<td></td>
</tr>
<tr>
<td>I, Total Direct and Indirect</td>
<td></td>
</tr>
<tr>
<td>J, Fee</td>
<td></td>
</tr>
<tr>
<td>K, Total Costs and Fee (I + J)</td>
<td></td>
</tr>
</tbody>
</table>
R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

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

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

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.

1) Please attach Attachment 1
2) Please attach Attachment 2
3) Please attach Attachment 3
4) Please attach Attachment 4
5) Please attach Attachment 5
6) Please attach Attachment 6
7) Please attach Attachment 7
8) Please attach Attachment 8
9) Please attach Attachment 9
10) Please attach Attachment 10
11) Please attach Attachment 11
12) Please attach Attachment 12
13) Please attach Attachment 13
14) Please attach Attachment 14
15) Please attach Attachment 15
16) Please attach Attachment 16
17) Please attach Attachment 17
18) Please attach Attachment 18
19) Please attach Attachment 19
20) Please attach Attachment 20
21) Please attach Attachment 21
22) Please attach Attachment 22
23) Please attach Attachment 23
24) Please attach Attachment 24
25) Please attach Attachment 25
26) Please attach Attachment 26
27) Please attach Attachment 27
28) Please attach Attachment 28
29) Please attach Attachment 29
30) Please attach Attachment 30
The PHS 398 Modular Budget form cannot be used if the application requests >$250K in direct costs in any budget period, is submitted by a foreign institution, or proposes the use of human fetal tissue from elective abortions.

**PHS 398 Modular Budget**

OMB Number: 0925-0001  
Expiration Date: 01/31/2026

### A. Direct Costs

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

**Consortium Indirect (F&A)**

**Total Direct Costs**

0.00

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

**Indirect (F&A) Type**

**Indirect (F&A)**

**Rate (%)**

**Indirect (F&A) Base ($)**

**Funds Requested ($)**

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**

<table>
<thead>
<tr>
<th>Section A, Total Direct Cost less Consortium Indirect (F&amp;A) for Entire Project Period</th>
<th>$ 0.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A, Total Consortium Indirect (F&amp;A) for Entire Project Period</td>
<td>$</td>
</tr>
<tr>
<td>Section A, Total Direct Costs for Entire Project Period</td>
<td>$ 0.00</td>
</tr>
<tr>
<td>Section B, Total Indirect (F&amp;A) Costs for Entire Project Period</td>
<td>$</td>
</tr>
<tr>
<td>Section C, Total Direct and Indirect (F&amp;A) Costs (A+B) for Entire Project Period</td>
<td>$ 0.00</td>
</tr>
</tbody>
</table>

**2. Budget Justifications**

Personnel Justification

Consortium Justification

Additional Narrative Justification

FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must provide this attachment and include a section titled "Data Management and Sharing Justification" that provides a brief summary of DMS activities and justification for their costs.
**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>First-Year/Soph.</td>
<td>Junior/Senior</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>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>
</tbody>
</table>

Stipends Requested ($) | Tuition/Fees Requested ($)

**B. Other Direct Costs**

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

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

**D. Indirect (F&A) Costs**

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

Total Indirect (F&A) Costs Requested

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

**F. Budget Justification**

Budget justification is required and must cover all budget periods.
A. Stipends, Tuition/Fees

| Undergraduate: |  |  |
| Single Degree |  |  |
| Dual Degree |  |  |
| **Total Predoctoral** |  |  |
| Predoctoral: |  |  |
| Non-Degree Seeking |  |  |
| Degree Seeking |  |  |
| **Total Postdoctoral** |  |  |
| Other: |  |  |
| **Totals:** |  |  |

**Total Stipends + Tuition/Fees Requested**  

| B. Other Direct Costs | Funds Requested ($) |
| Trainee Travel |  |
| Training Related Expenses |  |
| Total Direct Costs from R&R Budget Form (if applicable) |  |
| Consortium Training Costs (if applicable) |  |
| **Total Other Direct Costs Requested** |  |

| C. Total Direct Costs Requested (A + B) |  |
| D. 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.

Click here to extract the PHS 398 Training Subaward Attachment

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.

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

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.
**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.)

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

<table>
<thead>
<tr>
<th>Indirect Costs</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>System calculated.</td>
</tr>
</tbody>
</table>
# BUDGET INFORMATION - Construction Programs

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

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

**FEDERAL FUNDING**

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

Be sure to include the multiplier or the total will calculate to zero.
# PHS 398 Research Plan

## 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 funding opportunity. Typically 6 or 12 pages; a small number of funding opportunities 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. Other Plan(s)
12. Authentication of Key Biological and/or Chemical Resources  
   - Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.

## Appendix
13. Appendix  
   - DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the funding opportunity as allowed or required.
   - Allows for up to 10 appendices. See Application Guide and funding opportunity for restrictions.
   - Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.
# 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 funding opportunity.

## 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 funding opportunity.

5. **Progress Report Publication List**
   - Limited to 1 page.

6. **Training in the Responsible Conduct of Research**
   - Limited to 1 page.

## Other Candidate Information Section

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

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

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

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

## Environment and Institutional Commitment to Candidate Section

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

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

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

## Other Research Plan Sections

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

14. **Select Agent Research**

15. **Consortium/Contractual Arrangements**

16. **Resource Sharing**
   - FORMS-H: A single Data Management and Sharing plan required if research will generate scientific and/or large-scale genomic data. Recommended <= 2 pages. Typically not part of application image used for peer review; posted as separate document in eRA Commons.

17. **Other Plan(s)**

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

19. Appendix

* Citizenship

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

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

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

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

If no, select 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.

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
   - 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

13. Other Plan(s)
    - FORMS-H: NIH Data Sharing Policies are not applicable to institutional training applications. Attachment added for potential future use with other plans.

Appendix

14. Appendix
    - DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the funding opportunity as allowed or required.
    - Allows for up to 10 appendices. See Application Guide and funding opportunity for restrictions.
    - Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.
## Introduction

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

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

## Other Research Training Plan Section

### Vertebrate Animals

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

- **Are Vertebrate Animals Used?**
  - [ ] Yes
  - [ ] No

13. **Are vertebrate animals euthanized?**
    - [ ] Yes
    - [ ] No

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

   - **If “Yes” to euthanasia**
     - Is method consistent with American Veterinary Medical Association (AVMA) guidelines?
       - [ ] Yes
       - [ ] No

   - **If “No” to AVMA guidelines, describe method and provide scientific justification**
     - **Up to 1000 characters.**

14. **Vertebrate Animals**
    - Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.
Additional Information Section

19. 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:  
https://grants.nih.gov/stem_cells/registry/current.htm. 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 https://grants.nih.gov/stem_cells/registry/current.htm at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Add up to 200 cell lines.

20. Alternate Phone Number:

21. Degree Sought During Proposed Award:

Degree:  
If "other", indicate degree type:  
Expected Completion Date (MM/YYYY):

22. * Field of Training for Current Proposal:

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

23. * Current or Prior Kirschstein-NRSA Support?  

Yes  No

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

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

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

24. * Applications for Concurrent Support

Yes  No

If yes, describe in an attached file:

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

25. * Citizenship:

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

Yes  No

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

Non-U.S. Citizen with a Permanent U.S. Resident Visa

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

FORMS-H: NIH Data Sharing Policies are not applicable to fellowship applications. Attachment added for potential future use with other plans.
# PHS Fellowship Supplemental Form

## Budget Section

### All Fellowship Applicants:

27. * Tuition and Fees:

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

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

Total Funds Requested: 

### Applicants can request up to $2500 per year (NOT-OD-21-074).

28. * Childcare Costs:

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount</th>
<th>Academic Period</th>
<th>Number of Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></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.

29. Present Institutional Base Salary:

<table>
<thead>
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<th>Number of Months</th>
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<tbody>
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</tbody>
</table>

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

a. Federal Stipend Requested:

<table>
<thead>
<tr>
<th>Amount</th>
<th>Number of Months</th>
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</thead>
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b. Supplementation from Other Sources:

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

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

Source

## Appendix

31. Appendix

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

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

Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.
**Questions 1-8 must be completed by all SBIR and STTR Applicants:**

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

2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?  
   - [x] Yes  
   - [ ] No
   
   * If yes, insert the names of the Federal laboratories/agencies:

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

4. Will all research and development on the project be performed in its entirety in the United States?  
   - [x] Yes  
   - [ ] No
   
   * Explanation:  
     - [ ] Required if No. Cannot include if Yes.

5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?  
   - [ ] Yes  
   - [x] 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)?  
   - [x] Yes  
   - [ ] No

7. Does the application include a request of SBIR or STTR funds for Technical and Business Assistance (TABA)? If yes, please follow the agency specific instructions to provide the budget request and justification. (Please answer no if you plan to use the agency TABA vendor, which does not require you to include a request for TABA funds in your application.)  
   - [x] Yes  
   - [ ] No

8. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase III Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.  
   - [ ] Yes  
   - [x] No

---

**Form only included in small business funding opportunities.**

**Agency to which you are applying (select only one):**

- [ ] DOE  
- [x] HHS  
- [ ] USDA  
- [ ] Other: Check HHS for all NIH, CDC, and FDA submissions.

**SBC Control ID:**  
- [x] Required.

The 9-digit code is included in the registry filename received from SBA upon registration (e.g., SBC_123456789.pdf).

**Program Type (select only one):**

- [ ] SBIR  
- [x] 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  
- [x] 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.

---

NIH Office of Extramural Research  
FORMS-H Series (Updated March 28, 2023)  
Page 29
**SBIR/STTR Information**

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

Questions 9 and 10 apply only to SBIR applications. If you are submitting **ONLY** an STTR application, leave questions 9 and 10 blank and proceed to question 11.

- [ ] Yes
- [ ] No

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

*Attach File:*

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

- [ ] Yes
- [ ] No

*10. 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.*

Questions 11 - 13 apply only to STTR applications. If you are submitting **ONLY** an SBIR application, leave questions 11 - 13 blank.

- [ ] Yes
- [ ] No

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

1. Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; **AND**
2. Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?*

- [ ] Yes
- [ ] No

- [ ] Yes
- [ ] No

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

- [ ] Yes
- [ ] No

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

Enter the Unique Entity Identifier (UEI) of the non-profit research partner for the STTR applicant.
Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

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

Information populated from R&R Other Project Information form.

If No to Human Subjects

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

If Yes to Human Subjects

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

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

Other Requested Information

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

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

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

Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.

Delayed Onset Study(ies)

Study Title

Anticipated Clinical Trial?

Justification

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

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

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

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique) 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? If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

1.3. Exemption Number

1.4. * Clinical Trial Questionnaire Answers to questionnaire required and system enforced.

1.4.a. Does the study involve human participants? If four questions are all Yes AND funding opportunity allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.

1.4.b. Are the participants prospectively assigned to an intervention?

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

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

Section 2 - Study Population Characteristics

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

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

2.3. Age Limits

2.3.a. Inclusion of Individuals Across the Lifespan Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity.

2.3.b. Inclusion of Women and Minorities Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity.

2.5. Recruitment and Retention Plan Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity.

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s) Inclusion Enrollment Reports required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding 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.
PHS Inclusion Enrollment Report

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

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

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

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

5. Enrollment Location(s)

6. Comments
   Up to 500 characters.
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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 if study is not exempt from federal regulations (i.e., Question 1.2 is No).

Single IRB plan attachment

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

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 funding 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 funding opportunity does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose

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

4.1.c. Interventions

Up to 20 Interventions allowed.

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

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

4.3. Statistical Design and Power

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

4.4. Subject Participation Duration

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

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

☐ Yes  ☐ No

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

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

Required and system enforced if Yes.

4.6. Is this an applicable clinical trial under FDAAA?

☐ Yes  ☐ No

4.7. Dissemination Plan

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

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

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

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Funding Opportunity Number:

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

Awarding Component Assignment Suggestions (optional)

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

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

Suggested Awarding Components: 

Study Section Assignment Suggestions (optional)

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

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

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

Suggested Study Sections:

Rationale for assignment suggestions (optional)  

Entry is limited to 1000 characters.

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*

<table>
<thead>
<tr>
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</table>

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