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.

Table of Contents

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)

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

1. TYPE OF SUBMISSION

> Use Application for first submission attempt for due date.

- [ ] Pre-application
- [ ] Application
- [ ] Changed/Corrected Application

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).

b. Agency Routing Identifier

2. DATE SUBMITTED | **Applicant Identifier**

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

> Use Changed/Corrected when submitting again to Grants.gov for a due date (e.g., to correct eRA identified errors/warnings.)

c. Previous Grants.gov Tracking ID

> 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).

5. APPLICANT INFORMATION

UEI:

Legal Name:

Department: [100 characters.]   Division: [100 characters.]

Street1:

> 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.

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES   ZIP / Postal Code:

> Must provide zip+4 for all zip codes.

Person to be contacted on matters involving this application

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES   ZIP / Postal Code:

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

Other (Specify):

Small Business Organization Type   [ ] Women Owned   [ ] Socially and Economically Disadvantaged

> Do not use these Small Business Organization Type checkboxes. NIH/CDC/FDA use SAM data to gather this information.

8. TYPE OF APPLICATION:

> See application guide for definitions.

- [ ] New
- [ ] Resubmission
- [ ] Renewal
- [ ] Continuation
- [ ] Revision

If Revision, mark appropriate box(es).

- [ ] A. Increase Award
- [ ] B. Decrease Award
- [ ] C. Increase Duration
- [ ] D. Decrease Duration
- [ ] E. Other (specify):

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

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

TITLE:

> 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.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: [ ]   First Name: [ ]   Middle Name: [ ]

Last Name: [ ]   Suffix: [ ]

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

Position/Title: [ ]

Organization Name: [ ]

Department: [ ]   Division: [ ]

Street1: [ ]

Street2: [ ]

City: [ ]   County / Parish: [ ]

State: [ ]   Province: [ ]

Country: USA: UNITED STATES   ZIP / Postal Code: [ ]

Phone Number: [ ]   Fax Number: [ ]

Email: [ ]

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, ~~~

[ ] **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

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

19. Authorized Representative

Prefix: [ ]   First Name: [ ]   Middle Name: [ ]

Last Name: [ ]   Suffix: [ ]

Position/Title: [ ]

Organization: [ ]

Department: [ ]   Division: [ ]

Street1: [ ]

Street2: [ ]

> 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).

City: [ ]   County / Parish: [ ]

State: [ ]   Province: [ ]

Country: USA: UNITED STATES   ZIP / Postal Code: [ ]

Phone Number: [ ]   Fax Number: [ ]

Email: [ ]

Signature of Authorized Representative   **Date Signed**

[ ]   [ ]

20. Pre-application [ ]

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. 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.

PHS 398 Cover Page Supplement

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

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

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

2. *Program Income Section

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

☐ Yes ☐ No

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

*Budget Period   *Anticipated Amount ($)   *Source(s)

Up to 150 characters.

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

Required if Yes. Cannot be included if No. [Add Attachment] [Delete Attachment] [View Attachment]

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

Required if Yes. Cannot be included if No. [Add Attachment] [Delete Attachment] [View Attachment]

PHS 398 Cover Page Supplement

5. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents: Yes ☐   No ☐

If "**Yes**" then answer the following:

*Previously Reported: Yes ☐   No ☐

6. Change of Investigator/Change of Institution Section

☐ Change of Project Director/Principal Investigator

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

Name of former Project Director/Principal Investigator:

Prefix: _____

*First Name: _____

Middle Name: _____

*Last Name: ____ If change of PD/PI box is checked, you must provide the last name of the former PD/PI.

Suffix: _____

☐ Change of Grantee Institution

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

*Name of former institution:

If change of Grantee Institution box is checked, you must provide the name of former institution.

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved? ☐ Yes ☐ No

> If Human Subjects = Yes, additional information may be required on the PHS Human Subjects and Clinical Trials Information form.

1.a. If YES to Human Subjects

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

> Only answer Yes if all the proposed research human subject studies are exempt.

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

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

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date: _____

> IRB Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

Human Subject Assurance Number: _____

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

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

> If Vertebrate Animals = Yes, additional attachments are required in the PHS 398 Research Plan or equivalent form.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date: _____

> IACUC Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

Animal Welfare Assurance Number: _____

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

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

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

4.b. If yes, please explain: [If 4a is Yes, then 4b is required. Up to 55 characters.]

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

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

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

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

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

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

> If Yes, must include a "Foreign Justification" as an Other Attachment in item #12.

6.b. Optional Explanation: [Up to 55 characters.]

7. Project Summary/Abstract

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

8. Project Narrative

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

9. Bibliography & References Cited

> Required unless otherwise noted in opportunity. Not system enforced.

[View Attachment]

10. Facilities & Other Resources

> Required unless otherwise noted in opportunity. Limited system enforcement.

[View Attachment]

11. Equipment

> Required unless otherwise noted in opportunity. Limited system enforcement.

12. Other Attachments [Add Attachments] [Delete Attachments] [View Attachments] ☐

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

Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

Organization Name: [DO NOT check box. NIH only accepts applications from registered organizations.]

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

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

Project/Performance Site Location 1

☐ 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:   [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.]

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

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

Additional Location(s) [   ] [Add Attachment] [Delete Attachment] [View Attachment]

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

Prefix: _____   * First Name: _____   Middle Name: _____

* Last Name: _____   Suffix: _____

Position/Title: _____   Department: | 100 characters. |

Organization Name: _____   Division: | 100 characters. |

> Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.

* Street1: _____

Street2: _____

* City: _____   County/ Parish: _____

* State: _____   Province: _____

* Country: USA: UNITED STATES   * Zip / Postal Code: _____

* Phone Number: _____

* E-Mail: _____

Credential, e.g., agency login: _____

> **VALID & ACTIVE ERA COMMONS USERNAME MUST BE SUPPLIED.** Contact PD/PI must be affiliated in Commons with applicant organization. Commons account should not have both the PI and SO roles (if PD/PI also serves as SO, use a separate account for SO functions).
>
> ORCID iD must be associated with PD/PI eRA Commons Personal Profile of Fellowship and Career Development applications. Recommended for all.

* **Project Role:** PD/PI

> Project Role will default to PD/PI and must remain PD/PI (do not edit - we string match).

Degree Type: _____

Degree Year: _____

> Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm

***Attach Biographical Sketch** _____   Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support _____

> 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

Prefix: _____   * First Name: _____   Middle Name: _____

* Last Name: _____   Suffix: _____

Position/Title: _____   Department: | 100 characters. |

Organization Name: _____   Division: | 100 characters. |

> Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.

* Street1: _____

Street2: _____

* City: _____   County/ Parish: _____

* State: _____   Province: _____

* Country: USA: UNITED STATES   * Zip / Postal Code: _____

* Phone Number: _____   Fax Number: _____

* E-Mail: _____

Credential, e.g., agency login: _____

> 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.

* **Project Role:** _____   **Other Project Role Category:** _____

Degree Type: _____

Degree Year: _____

> Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm

Attach Biographical Sketch _____   Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support _____

> Only provide Current & Pending Support if specifically requested in funding opportunity. May be requested later in pre-award process as Just-In-Time data.

| Delete Entry | | Next Person |

> Can collect data for 100 Sr/Key personnel (including PD/PI). Option to provide attachment for additional Sr/Key info is available after the 100 entries are made. See Additional Senior/Key Person Profiles format page at: https://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm.

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

UEI: ⬇️ Enter name of Organization: [   ]

Budget Type: ☐ Project ☐ Subaward/Consortium   Budget Period: 1 Start Date: [   ] End Date: [   ]

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

A. Senior/Key Person

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

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 ($)	Months Cal.	Acad.	Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)

Project Role: PD/PI

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

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

Additional Senior Key Persons: [   ] [Add Attachment] [Delete Attachment] [View Attachment]

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

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

Total Senior/Key Person [   ]

B. Other Personnel

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

Number of Personnel	Project Role	Months Cal.	Acad.	Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

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) [   ]

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

Equipment item	Funds Requested ($)

Additional Equipment: [   ]

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

[View Attachment]

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

D. Travel

Funds Requested ($)

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

E. Participant/Trainee Support Costs

Funds Requested ($)

1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	

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

[ ]	**Number of Participants/Trainees**	
	Total Participant/Trainee Support Costs	

F. Other Direct Costs

		Funds Requested ($)
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.		

> Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.

9.	
10.	
11.	
12.	
13.	
14.	
15.	
16.	
17.	

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

Total Other Direct Costs _____

G. Direct Costs

Funds Requested ($)

Total Direct Costs (A thru F) _____

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)

Total Indirect Costs _____

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

I. Total Direct and Indirect Costs

Funds Requested ($)

Total Direct and Indirect Institutional Costs (G + H) _____

J. Fee

Funds Requested ($)

_____

K. Total Costs and Fee

Funds Requested ($)

Total Costs and Fee (I + J) _____

L. Budget Justification

(Only attach one file.) [_____] [Add Attachment] [Delete Attachment] [View Attachment]

> 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.

RESEARCH & RELATED BUDGET - Cumulative Budget

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

Totals ($)

Section A, Senior/Key Person

Section B, Other Personnel

Total Number Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)

Section C, Equipment

Section D, Travel

1. Domestic

2. Foreign

Section E, Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

6. Number of Participants/Trainees

Section F, Other Direct Costs

1. Materials and Supplies

2. Publication Costs

3. Consultant Services

4. ADP/Computer Services

5. Subawards/Consortium/Contractual Costs

6. Equipment or Facility Rental/User Fees

7. Alterations and Renovations

8. Other 1

9. Other 2

10. Other 3

11. Other 4

12. Other 5

13. Other 6

14. Other 7

15. Other 8

16. Other 9

17. Other 10

Section G, Direct Costs (A thru F)

Section H, Indirect Costs

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

Section J, Fee

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

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.

<div style="text-align:center;">

Click here to extract the R&R Subaward Budget Attachment

</div>

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 | Add Attachment | Delete Attachment | View Attachment
2) Please attach Attachment 2 | Add Attachment | Delete Attachment | View Attachment
3) Please attach Attachment 3 | Add Attachment | Delete Attachment | View Attachment
4) Please attach Attachment 4 | Add Attachment | Delete Attachment | View Attachment
5) Please attach Attachment 5 | Add Attachment | Delete Attachment | View Attachment
6) Please attach Attachment 6 | Add Attachment | Delete Attachment | View Attachment
7) Please attach Attachment 7 | Add Attachment | Delete Attachment | View Attachment
8) Please attach Attachment 8 | Add Attachment | Delete Attachment | View Attachment
9) Please attach Attachment 9 | Add Attachment | Delete Attachment | View Attachment
10) Please attach Attachment 10 | Add Attachment | Delete Attachment | View Attachment
11) Please attach Attachment 11 | Add Attachment | Delete Attachment | View Attachment

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.

12) Please attach Attachment 12 | Add Attachment | Delete Attachment | View Attachment
13) Please attach Attachment 13 | Add Attachment | Delete Attachment | View Attachment
14) Please attach Attachment 14 | Add Attachment | Delete Attachment | View Attachment
15) Please attach Attachment 15 | Add Attachment | Delete Attachment | View Attachment
16) Please attach Attachment 16 | Add Attachment | Delete Attachment | View Attachment
17) Please attach Attachment 17 | Add Attachment | Delete Attachment | View Attachment
18) Please attach Attachment 18 | Add Attachment | Delete Attachment | View Attachment
19) Please attach Attachment 19 | Add Attachment | Delete Attachment | View Attachment
20) Please attach Attachment 20 | Add Attachment | Delete Attachment | View Attachment
21) Please attach Attachment 21 | Add Attachment | Delete Attachment | View Attachment
22) Please attach Attachment 22 | Add Attachment | Delete Attachment | View Attachment
23) Please attach Attachment 23 | Add Attachment | Delete Attachment | View Attachment
24) Please attach Attachment 24 | Add Attachment | Delete Attachment | View Attachment
25) Please attach Attachment 25 | Add Attachment | Delete Attachment | View Attachment
26) Please attach Attachment 26 | Add Attachment | Delete Attachment | View Attachment
27) Please attach Attachment 27 | Add Attachment | Delete Attachment | View Attachment
28) Please attach Attachment 28 | Add Attachment | Delete Attachment | View Attachment
29) Please attach Attachment 29 | Add Attachment | Delete Attachment | View Attachment
30) Please attach Attachment 30 | Add Attachment | Delete Attachment | View Attachment

PHS 398 Modular Budget

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

Budget Period: 1   Form allows for up to 5 Budget Periods.

Start Date: [ ]   End Date: [ ]

A. Direct Costs

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.

	Funds Requested ($)
Direct Cost less Consortium Indirect (F&A)	0.00
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 for four F&A entries.			

Cognizant Agency (Agency Name, POC Name and Phone Number) [ ]

Indirect (F&A) Rate Agreement Date [ ]   Total Indirect (F&A) Costs [ ]

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

Funds Requested ($) [0.00]

Cumulative Budget Information   System calculated.

1. Total Costs, Entire Project Period

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

2. Budget Justifications

Personnel Justification	[ ]	Add Attachment	Delete Attachment	View Attachment
Consortium Justification	[ ]	Add Attachment	Delete Attachment	View Attachment
Additional Narrative Justification	[ ]	Add Attachment	Delete Attachment	View Attachment

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 brief summary of DMS activities and justification for their costs.

PHS 398 TRAINING BUDGET, Period 1

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

Only the applicant organization should use Project.

UEI: [   ]   Budget Type: ☐ Project   ☐ Subaward/Consortium

Organization Name: [   ]

Start Date: [   ]   End Date: [   ]

The end date for each budget period must be later than the budget start date and less than or equal to the proposed project end date listed on the SF 424 (R&R) cover.

A. Stipends, Tuition/Fees

For New and Resubmission applications, the first budget period start date must match the start date listed on the SF 424 (R&R) cover. The start date in subsequent periods must be greater than or equal to the start date on the cover.

Number of Trainees

Error if information for Undergraduate Trainees is NOT provided for T34 applications and if it IS provided for T15, T32 or T35 applications.

Full Time	Short Term		Stipends Requested ($)	Tuition/Fees Requested ($)
[ ]	[ ]	Undergraduate:	[ ]	[ ]

Number Per Stipend Level:

First-Year/Soph. [ ]   Junior/Senior [ ]

Full Time	Short Term		Stipends Requested ($)	Tuition/Fees Requested ($)
[ ]	[ ]	Predoctoral: Single Degree	[ ]	[ ]
[ ]	[ ]	Dual Degree	[ ]	[ ]
[ ]	[ ]	**Total Predoctoral**	[ ]	[ ]

Error if any Predoctoral or Postdoctoral information is provided for T34.

Postdoctoral: Number Per Stipend Level:

			0	1	2	3	4	5	6	7		
[ ]	[ ]	Non-degree Seeking	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	Degree Seeking	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	**Total Postdoctoral**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

Full Time	Short Term		Stipends Requested ($)	Tuition/Fees Requested ($)
[ ]	[ ]	Other:	[ ]	

If Number of Trainees data is provided then corresponding Stipends Requested data must also be provided and vice versa.

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)	[ ]

Warning if not provided.

Must be manually entered.

Include sum of all attached Training Subaward Budget forms.

Total Other Direct Costs Requested [ ]

C. Total Direct Costs Requested (A + B) [ ]

D. Indirect (F&A) Costs

	Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base	Funds Requested ($)
1.	[ ]	[ ]	[ ]	[ ]
2.	[ ]	[ ]	[ ]	[ ]

Indirect Cost Rate must be 8 for all Ts.

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.

[ ]ent   [View Attachment]

PHS 398 TRAINING BUDGET, Cumulative Budget

Values are system calculated.

A. Stipends, Tuition/Fees

		Stipends Requested ($)	Tuition/Fees Requested ($)
Undergraduate:			
Predoctoral:	Single Degree		
	Dual Degree		
	Total Predoctoral		
Postdoctoral:	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)

The actual look of this form will vary based on your submission method. In ASSIST, use the Add Optional Form action to add the Training Subaward Budget tab to your application.

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

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.

Optional form in Overall component of multi-project applications only. Used to gather additional indirect cost information needed from the applicant organization to correctly calculate an application's indirect costs when entire components are led by collaborating organizations.

PHS Additional Indirect Costs - Budget Period 1

Provide the 12 alpha-numeric character Unique Entity Identifier for the applicant organization.

UEI: [   ]   **Enter name of Organization:** [   ]

Budget Type: ☐ Project   ☐ Subaward/Consortium   **Budget Period: 1**   *** Start Date:** [   ]   *** End Date:** [   ]

Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	**Funds Requested ($)**
[ ]	[ ]	[ ]	[ ]

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.

PHS Additional Indirect Costs - Cumulative Budget

Totals ($)

System calculated.

Indirect Costs

BUDGET INFORMATION - Construction Programs

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

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

Total Allowable Costs (Columns a-b) are system verified.

FEDERAL FUNDING

17. Federal assistance requested, calculate as follows:
(Consult Federal agency for Federal percentage share.)
Enter the resulting Federal 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.

   View Attachment

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.

   Attachment

Other Research Plan Section

5. Vertebrate Animals

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

   View Attachment

6. Select Agent Research

   Add Attachment | Delete Attachment | View Attachment

7. Multiple PD/PI Leadership Plan

   Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.

8. Consortium/Contractual Arrangements

   Add Attachment | Delete Attachment | View Attachment

9. Letters of Support

   Required for R36 applications.

   Add Attachment | Delete Attachment | View Attachment

10. Resource Sharing Plan(s)

    Add Attachment | Delete Attachment | View Attachment

11. Other Plan(s)

    FORMS-H: Include a single Data Management and Sharing plan, if required. See Application Guide and funding opportunity. Recommended <= 2 pages. Typically not part of application image used for peer review; posted as separate document in eRA Commons.

12. Authentication of Key Biological and/or
    Chemical Resources

    Add Attachment | Delete Attachment | View Attachment

    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
   (for Resubmission and Revision applications)

   Required for Resubmission and Revision applications. Must not be included for New or Renewal applications. Limited to 1 page.
   [View Attachment]

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.
   [Attachment]

Research Plan Section

3. Specific Aims

   Required. Limited to 1 page.
   [Add Attachment] [Delete Attachment] [View Attachment]

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
   (for Renewal applications)

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

6. Training in the Responsible Conduct of Research

   Required. Limited to 1 page.
   [Add Attachment] [Delete Attachment] [View Attachment]

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.
   [Attachment]

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.
   [ment] [View Attachment]

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

   Limited to 6 pages.
   [Add Attachment] [Delete Attachment] [View Attachment]

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment

    Required. Limited to 1 page.
    [Add Attachment] [Delete Attachment] [View Attachment]

11. Institutional Commitment to Candidate's Research Career Development

    Required. Limited to 1 page.
    [Add Attachment] [Delete Attachment] [View Attachment]

12. Description of Candidate's Contribution to Program Goals

    Required for diversity-related funding opportunities only.
    [Delete Attachment] [View Attachment]

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

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

15. Consortium/Contractual Arrangements

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

16. Resource Sharing

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

17. Other Plan(s)

    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.

18. Authentication of Key Biological and/or Chemical Resources

    Required if project involves key biological and/or chemical resources. No system validation enforcement.
    [ment] [View Attachment]

PHS 398 Career Development Award Supplemental Form

Appendix

19. Appendix

[Add]

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.

* Citizenship

20. * U.S. Citizen or Non-Citizen National?   ☐ Yes   ☐ No

Not allowed for K43.

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

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

Not allowed for K43.   ☐ With a Permanent U.S. Resident Visa

Not allowed for K43.   ☐ 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: ☐

PHS 398 Research Training Program Plan

Introduction

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

   Required for Resubmission applications; limited to 3 pages.
   Required for Revision applications; limited to 1 page.

   Delete Attachment | View Attachment

Training Program Section

2. * Program Plan

   Required. Limited to 25 pages.

   Add Attachment | Delete Attachment | View Attachment

3. Plan for Instruction in the Responsible Conduct of Research

   Required. Limited to 3 pages.

   Add Attachment | Delete Attachment | View Attachment

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.

   Add Attachment | Delete Attachment | View Attachment

Faculty, Trainees and Training Record Section

7. Participating Faculty Biosketches

   Warning if not included.

   Add Attachment | Delete Attachment | View Attachment

8. Letters of Support

   Add Attachment | Delete Attachment | View Attachment

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

    Add Attachment | Delete Attachment | View Attachment

12. Consortium/Contractual Arrangements

    Add Attachment | Delete Attachment | View Attachment

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

    Add Attachments | Delete Attachments | View Attachments

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

Introduction

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

Fellowship Applicant Section

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

Research Training Plan Section

3. * Specific Aims	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment
4. * Research Strategy	Required. Limited to 6 pages.	Add Attachment	Delete Attachment	View Attachment
5. * Respective Contributions	Required. Limited to 6 pages.	Add Attachment	Delete Attachment	View Attachment
6. * Selection of Sponsor and Institution	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment
7. Progress Report Publication List (for Renewal applications)		Add Attachment	Delete Attachment	View Attachment
8. * Training in the Responsible Conduct of Research	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment

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

| 9. Sponsor and Co-Sponsor Statements | Required. Limited to 6 pages. | Add Attachment | Delete Attachment | View Attachment |
| 10. Letters of Support from Collaborators, Contributors, and Consultants | Limited to 6 pages. | Add Attachment | Delete Attachment | View Attachment |

Institutional Environment and Commitment to Training Section

| 11. Description of Institutional Environment and Commitment to Training | Required for F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00. Limited to 2 pages. Includes Additional Education Information for F30 and F31 applications. | ...tachment |
| 12. Description of Candidate's Contribution to Program Goals | Required for diversity-related funding opportunity only. | ...ent | Delete Attachment | View Attachment |

Other Research Training Plan Section

Vertebrate Animals

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

Are Vertebrate Animals Used? ☐ Yes ☐ No

| 13. Are vertebrate animals euthanized? | ☐ Yes ☐ No | Answer required if Vertebrate Animals Used is Yes on the R&R Other Project Information form. |

If "**Yes**" to euthanasia

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

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

Up to 1000 characters.

| 14. Vertebrate Animals | Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form. |

PHS Fellowship Supplemental Form

Other Research Training Plan Information

15. Select Agent Research   [_____]   [Add Attachment]   [Delete Attachment]   [View Attachment]

16. Resource Sharing Plan   [_____]   [Add Attachment]   [Delete Attachment]   [View Attachment]

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

17. Other Plan(s)

18. 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.

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): [_____]   [Reset Entry]

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

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

If yes, identify current and prior Kirschstein-NRSA sup...

* Level	* Type	Start Date *(if known)*	End Date *(if known)*	Grant Number *(if known)*	
[_____]	[_____]	[_____]	[_____]	[_____]	[Reset Entry]

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

24. * Applications for Concurrent Support   [ ] Yes   [ ] No

If yes, describe in an attached file: [_____]

> Limited to 1 page.

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

> 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 a Permanent U.S. Resident Visa

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

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

[ ] With a Temporary U.S. Visa

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

PHS Fellowship Supplemental Form

26. ☐ Change of Sponsoring Institution

Name of Former Institution:

Required if 'Change of Sponsoring Institution' box is checked.

Budget Section

All Fellowship Applicants:

27. * Tuition and Fees: ☐ None Requested ☐ Funds Requested:

Year 1	
Year 2	
Year 3	
Year 4	
Year 5	
Year 6 (when applicable)	
Total Funds Requested:	

28. * Childcare Costs: ☐ None Requested ☐ Funds Requested:

Year 1	
Year 2	
Year 3	
Year 4	
Year 5	
Year 6 (when applicable)	
Total Funds Requested:	

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

Senior Fellowship Applicants Only:

Fields in this section are required for F33.

	Amount	Academic Period	Number of Months	
29. Present Institutional Base Salary:				Reset Entry

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

	Amount	Number of Months
a. Federal Stipend Requested:		

	Amount	Number of Months
b. Supplementation from Other Sources:		

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

Source

Appendix

31. Appendix   [Add Attachments] [Delete Attachments] [View Attachments]

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

SBIR/STTR Information

Form only included in small business funding opportunities.

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

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

☐ DOE   ☐ HHS   ☐ USDA   ☐ Other: _____   Check HHS for all NIH, CDC, and FDA submissions.

* SBC Control ID: [Required.]   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   ☐ STTR   Must select SBIR or STTR (not Both).

☐ 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)

SBIR only (if allowed in funding opportunity).   Not valid for HHS (NIH, CDC, FDA).   Not valid for HHS (NIH, CDC, FDA).

☐ Phase I   ☐ Phase II   ☐ Fast-Track   ☑ Direct Phase II   ☑ Phase IIA   ☐ Phase IIB   ☑ Phase IIC

☐ Commercialization Readiness Program   *(See agency-specific instructions to determine application type participation.)*   Check funding opportunity for allowable Application Types.

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

* Agency Topic/Subtopic: [Optional.]

Questions 1-8 must be completed by all SBIR and STTR Applicants:

☐ Yes ☐ No	*** 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.]
☐ Yes ☐ No	*** 1c.** Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? Selection required.
☐ Yes ☐ No	*** 1d.** Is your small business a Faculty or Student-Owned entity? Selection required.
☐ Yes ☐ No Selection required.	*** 2.** Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? *** If yes, insert the names of the Federal laboratories/agencies:** Required if Yes. Up to 250 characters. Cannot include if No.
☐ Yes ☐ No Selection required.	*** 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 ☐ No Selection required.	*** 4.** Will all research and development on the project be performed in its entirety in the United States? If no, provide an explanation in an attached file. *** Explanation:** Required if No. Cannot include if Yes. [Add Attachment] [Delete Attachment] [View Attachment]
☐ Yes ☐ No Selection required.	*** 5.** Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? *** If yes, insert the names of the other Federal agencies:** Required if Yes. Up to 250 characters. Cannot include if No.
☐ Yes ☐ No Selection required.	*** 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)?
☐ Yes ☐ No Selection required.	*** 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.) FORMS-G: New question.
	* 8. 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. *** Attach File:** _____ Required for Phase II, Direct Phase II, Phase IIB, Phase1/Phase II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.

SBIR/STTR Information

SBIR-Specific Questions:

Answers only required for SBIR applications.

Questions 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

* 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?

* 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.

PHS Human Subjects and Clinical Trials Information

Use of Human Specimens and/or Data

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

> Answer required for all applications.

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

Delayed Onset Study(ies)

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

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

Study Title	Anticipated Clinical Trial?	Justification
	☐	[Add Attachment] [Delete Attachment] [View Attachment]

> 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.

Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form.

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

*Always required field

Section 1 - Basic Information

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

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

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No — Answer required and system enforced.

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

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 defaults to Yes and is not editable.

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

If four questions are all Yes AND funding opportunity allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.

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

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required and system enforced unless 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.

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

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

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

2.3. Age Limits   **Minimum Age** [   ]   **Maximum Age** [   ]

If "N/A (No Limit)" selected, do not provide numerical min/max age.

2.3.a. Inclusion of Individuals Across the Lifespan   Required and system enforced unless exemption 4 is only exemption selected.   [Attachment] [View Attachment]

2.4. Inclusion of Women and Minorities   Required and system enforced unless exemption 4 is only exemption selected.   [Attachment]

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

2.6. Recruitment Status   Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in funding opportunity.

2.7. Study Timeline   Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in funding opportunity.   [Attachment] [View Attachment]

2.8. Enrollment of First Participant   Date: MM/DD/YYYY.   Dropdown list: Anticipated, Actual   Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset.

2.9. Inclusion Enrollment Report(s)

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

[Add Inclusion Enrollment Report]

Up to 20 Inclusion Enrollment Reports can be added.

* 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.

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.

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual)

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Report 1 of 1

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.] [...ent] [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.]

Intervention Type	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)
Name	Up to 200 characters.
Description	Up to 1,000 characters.

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

Name	Up to 255 characters.
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

4.3. Statistical Design and Power   Required and system enforced for CT study unless otherwise noted in funding opportunity. | ...ment | Delete Attachment | View Attachment |

4.4. Subject Participation Duration   Up to 255 characters. Required and system enforced for CT studies 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. | Add Attachment | Delete Attachment | View Attachment |

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

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

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments | Add Attachments | Delete Attachments | View Attachments |

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

PHS Assignment Request Form

Funding Opportunity Number:

Pre-populated from funding opportunity information.

Funding Opportunity Title:

Awarding Component Assignment Suggestions (optional)

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

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

Suggested Awarding Components:

Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Study Section Assignment Suggestions *(optional)*

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

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

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

Suggested Study Sections:
Only 20 characters allowed

Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Rationale for assignment suggestions *(optional)*   *Entry is limited to 1000 characters.*

Up to 1000 characters.

PHS Assignment Request Form

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

Provide sufficient information (e.g., name organization affiliation) to correctly identify each individual. Provide specific reason why an individual should not review your application. Information will be considered, but listing an individual does not guarantee they will not be on review panel.

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

	1	2	3	4	5
Expertise: *Each entry is limited to 40 characters*					

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