NIH Multi-project Applications: Annotated SF424 (R&R) Form Set

Forms-E Series

Multi-project applications are comprised of overall application information, one or more sets of component information and system-generated summary information.

The data collected at the Overall application level are the same for all multi-project applications. The data items collected for components depend on the component type and may vary from one component type to another.

Multi-project Component Forms

Page #	Form	Overall	Admin Core, Core, Project, Other named components	Indiv Career Dev	Career Dev	NRSA Training
	Forms Common to Most Components					
2	SF424 R&R cover	✓	✓	✓	✓	✓
4	PHS 398 Cover Page Supplement	✓	✓	✓	✓	✓
6	R&R Other Project Information	✓	✓	✓	✓	✓
7	Project/Performance Sites	✓	✓	✓	✓	✓
8	R&R Sr/Key Person Profile (Expanded)	✓	✓	✓	✓	✓
9	PHS Human Subjects and Clinical Trials Information	✓	✓	✓	✓	✓
15	PHS Assignment Request Form	Optional				
	Budget Forms					
17	R&R Budget		✓	✓	✓	
21	R&R Subaward Budget Attachment		Optional	Optional	Optional	
22	PHS 398 Training Budget					✓
24	Training Subaward Budget Attachment Form					Optional
25	PHS Additional Indirect Costs	Optional				
	Research Plan and Equivalent Forms					
27	PHS 398 Research Plan	✓	✓			
28	PHS 398 Career Development Award Supplemental Form			✓		
30	PHS 398 Research Training Program Plan				✓	✓

NOTES:

- The Funding Opportunity Announcement (FOA) and associated application guide remain the official documents for defining application requirements. This resource is meant to complement, not replace, those documents.
- NIH application packages include a subset of the forms included in this resource. You will only need to complete the forms provided to you with a specific FOA.
- The actual display of the forms depends on your submission method (ASSIST or system-to-system solution). The same forms, form fields and guidance apply regardless of submission option display differences.
- This resource is for FORMS-E application packages, see Do I Have the Right Forms for My Application?
- Registration in multiple systems is needed prior to submission, see Get Registered! Can take 6 weeks – start early!
- The blue annotations throughout this resource represent processing notes and eRA system business rule checks (i.e., validations).

NIH National Institutes of Health
Office of Extramural Research

All SF424 R&R fields are collected in Overall Component. Only fields 5,7 (optional), 11 and 12 collected in other

SF 424 (R&R)

1. TYPE OF SUBMISSION

☐ Pre-application ☐ Application ☐ Changed/Corrected Application

Use Application for first submission attempt for due date.

Do not use Pre-application unless specifically noted in FOA.

Use Changed/Corrected when submitting again to Grants.gov to correct eRA identified errors/ warnings.

2. DATE SUBMITTED | **Applicant Identifier**

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

4. a. Federal Identifier

b. Agency Routing Identifier

c. Previous Grants.gov Tracking ID

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

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

5. APPLICANT INFORMATION

Organizational DUNS:

Legal Name:

Department: Division:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

ASSIST: For Overall component, the Applicant information address fields are populated from the Commons institution Profile and are not editable.

Must be 9 or 13 digits; no letters or special characters.
Overall: Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations.
Other components: SAM and eRA Commons registration not required.

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):*

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

Other (Specify):

Overall: Required.
Other components: Optional.

Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

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:

NIH will assign CFDA post-submission.

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

If Revision (box 8), provide exact title (including punctuation and spacing) as provided for awarded grant. Limited to 200 characters.

12. PROPOSED PROJECT:

Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

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

Start date is an estimate; typically at least nine months after submission.
Project period should not exceed what is allowed in announcement.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

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.

Organization Name:

Department: Division:

ASSIST: For Overall component, the PD/PI information is pulled from the PD/PI section of the R&R Sr/Key Person Profile form and must be changed on that form.

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Phone Number: Fax Number:

Email:

15. ESTIMATED PROJECT FUNDING

Manually enter estimated project funding amounts.

a. Total Federal Funds Requested

b. Total Non-Federal Funds

c. Total Federal & Non-Federal Funds

d. Estimated Program Income

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

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

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

☐ **I agree**

See the NIH Grants Policy Statement for more information: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm

**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:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Phone Number: Fax Number:

Email:

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).

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

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 3/31/2020

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

If Yes on any component, then must be Yes on the Overall component.

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.

2. *Program Income Section

If Yes on any component, then must be Yes on the Overall component.

*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.

Accommodates up to 10 budget periods.

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

Up to 150 characters.

ASSIST: Program income details must be entered in Other components; data entry blocked in Overall.

Budget Period, Anticipated Amount, and Source information is not collected in the Overall component. A summary will be generated from information collected in other components.

ASSIST: Summary is available using "Preview Application".

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

If Yes, then must enter cell line entries or check the "cannot be referenced" box. If Yes on any component, then must be Yes on Overall component.

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

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

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

Only check 'cell line cannot be referenced' in Overall component if no cell lines are referenced on any component.

Cell Line(s) (Example: 0004):

Error if provided human embryonic stem cell lines (e.g., 0024, 0139) are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Form accommodates up to 200 cell lines.

Stem cell lines are not collected in the Overall component. A summary will be generated from information collected in other components.

ASSIST: Summary is available using "Preview Application".

ASSIST: Cell lines must be entered in Other components; data entry blocked in Overall.

4. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents: Yes ☐ No ☐

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

*Previously Reported: Yes ☐ No ☐

PHS 398 Cover Page Supplement

5. Change of Investigator/Change of Institution Section

☐ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. If YES to Human Subjects

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

If Overall exemption number is only 4, then no other exemption number can be set for any other component. For E4 requirements, see http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm#259

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

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

IRB Approval Date:

Overall: Future date not allowed. Date is not required at time of submission, but may be requested later as Just-In-Time data. Other components: not collected.

Human Subject Assurance Number:

Overall: If Human Subjects = Yes, then Human Subject Assurance Number or the text 'None' must be provided. Other components: not collected.

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:

Overall: Future date not allowed. Date is not required at time of submission, but may be requested later as Just-In-Time data. Other components: not collected.

Animal Welfare Assurance Number:

Overall: If Vertebrate Animals = Yes, then Animal Welfare Assurance Number or the text 'None' must be provided. Other components: not collected.

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

If Yes on any component, then must be Yes on Overall component.

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 6a is required. Up to 55 characters.

6.b. Optional Explanation:

Up to 55 characters.

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

7. Project Summary/Abstract

Required for all components: Succinct project summary of proposed work. Typically 30 lines or less; system will give error if over 1 page. Becomes public if awarded. Don't 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. Overall: Required. Other components: optional - see funding opportunity announcement for instructions.

9. Bibliography & References Cited

User-defined bookmarks are included with the bookmarks for the assembled application image in eRA Commons. Choice to include in Overall, other components or both unless noted otherwise in the FOA.

10. Facilities & Other Resources

Choice to include in Overall, other components or both unless noted otherwise in the FOA.

11. Equipment

User-defined bookmarks are included with the bookmarks for the assembled application image in eRA Commons. Choice to include in Overall, other components or both unless noted otherwise in the FOA.

12. Other Attachments Add Attachments Delete Attachments View Attachments

Only provide Other Attachments when requested in the funding opportunity announcement text or application guide. Use filename requested in announcement or application guide. If no filename is provided, use a meaningful filename since the filename will become a bookmark in the assembled application image.

Field accommodates multiple attachments.

Overall: Include Primary Site only. Other components: Include sites relevant to each component.

Project/Performance Site Location(s)

ASSIST: Option to populate from SF424 (R&R) cover.

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.

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

Organization Name:

DUNS Number:

DUNS required and enforced by NIH. Must be 9 or 13 digits; no letters or special characters.

* 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:

DUNS Number:

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 and 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/additional-performance-site.htm

Additional Location(s) Add Attachment Delete Attachment View Attachment

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components is generated upon submission.

ASSIST: Summary Performance Site information is available using "Preview Application".

ASSIST: Option to pull application profile information from eRA Commons profile or entries already included in another component.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

ASSIST: PD/PI profile information used to populate PD/PI information on SF424 (R&R) form.

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

Position/Title: Department:

Organization Name:

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:

VALID ERA COMMONS USERNAME MUST BE SUPPLIED. Overall: Contact PD/PI must be affiliated in Commons with applicant organization.

*** Project Role:** PD/PI **Other Project Role Category:**

Overall: Project Role must be PD/PI. Other components: Project Role can't be PD/PI.

ASSIST: For other components. Project Role defaults to Other with an Other Project Role Category of Project Lead.

Degree Type:

Degree Year:

***Attach Biographical Sketch**

Attach Current & Pending Support

Each Sr/Key person is allowed one biosketch for the entire application. When participating on multiple components, chose any single entry to attach biosketch and make sure it reflects participation on each component. Limited to 5 pages. Format and samples: http://grants.nih.gov/grants/forms/biosketch.htm.

Only provide Current & Pending Support if specifically requested in FOA. 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:

Organization Name: Division:

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:

Overall: For multiple PD/PI applications, you must use the PD/PI role and provide the eRA Commons username in the Credential field for all PD/PIs. When multiple PD/PIs are included, the Multiple PD/PI Leadership Plan on the Research Plan form is required.

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

Degree Type:

Degree Year:

Attach Biographical Sketch

Attach Current & Pending Support

Each Sr/Key person is allowed one biosketch for the entire application. When participating on multiple components, chose any single entry to attach biosketch and make sure it reflects participation on each component. Limited to 5 pages. Format and samples: http://grants.nih.gov/grants/forms/biosketch.htm.

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

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.

A summary of Sr/Key persons starting with PD/PI(s) then listing all others in alphabetical order will appear in the Overall section of the assembled application image in eRA Commons upon submission. The Sr/Key persons summary is followed by all biosketched in the same order.

ASSIST: Sr/Key personnel and biosketch summaries available using "Preview Application".

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: 03/31/2020

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

Answer required and system enforced when human subjects is No.

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

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

Required if Yes to human specimens/data question.

Add Attachment | Delete Attachment | View Attachment

When human subjects is No, applicants answer a single question, provide associated attachment (as applicable), and are done with the form unless instructed in announcement to include Other Requested Information attachment.

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

If Yes to Human Subjects

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

Other Requested Information

When work for a protocol is done across multiple components, enter the Study Record (including inclusion reporting information) in the Overall component to avoid duplication and use the Other Requested Information attachment for cross-referencing. In the Overall, the attachment must indicate which components will be working on the protocol. In the Other Components, the attachment must indicate the study record details can be found in the Overall component.

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Overall: Only include a study record if it reflects a protocol used by more than one component.
Other components: If all work for a protocol is done within a single component, then that protocol should be reflected in a study record within the component itself.

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.

Multiple delayed onset studies can be grouped in a single record if desired.

	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 announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

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

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

Overall: Only include a study record if it reflects a protocol used by more than one component. Other components: If all work for a protocol is done within a single component, then that protocol should be reflected in a study record within the component itself.

Study Record: PHS Human Subjects and Clinical Trials Information

HS = Human Subjects
CT = Clinical Trials

OMB Number: 0925-0001
Expiration Date: 03/31/2020

* 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.

1.4. * Clinical Trial Questionnaire

Answers to questionnaire required and system enforced.

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

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

If four questions are all Yes AND FOA 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# if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application and typically would not have an NCT#.

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

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

2.2. Eligibility Criteria

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

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

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

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

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

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

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

Drop down: Not yet recruiting, Recruiting, Enrolling by invitation, Active, not recruiting, Completed, Suspended, Terminated (Halted Prematurely), Withdrawn (No Participants Enrolled)

2.7. Study Timeline Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.8. Enrollment of First Subject Date: MM/DD/YYYY. Drop down: Anticipated, Actual

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

Inclusion Enrollment Report(s)

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

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource ☐ Yes ☐ No

Answer required and system enforced.

2. * Enrollment Location Type ☐ Domestic ☐ Foreign

Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

3. Enrollment Country(ies)

Multi-select from list of countries.

4. Enrollment Location(s)

5. Comments

Up to 500 characters.

Planned

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

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	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									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			**Total**
	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 for fellowship, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan — Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies. Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan — Required and system enforced for CT study. Optional for HS study. Add Attachment | Delete Attachment | View Attachment

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

☐ Yes ☐ No — Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team — Optional. Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis

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

4.1. Brief Summary

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

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

4.2.a. Narrative Study Description

Up to 32,000 characters.

4.2.b. Primary Purpose — Primary Purpose drop down list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; and Device Feasibility

Screening
Health Services Research
Basic Science
Device Feasibility
Other

4.2.c. Interventions — Up to 20 Interventions allowed.

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

Intervention Type drop down 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)

Combination Product
Diagnostic Test
Other

Early Phase 1 (or Phase 0)
Phase 1
Phase 1/2

4.2.d. Study Phase — Study Phase drop down list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and Other

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

4.2.e. Intervention Model — Intervention Model drop down list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.

Factorial
Sequential
Other

4.2.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

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

4.2.g. Allocation

Allocation drop down list: N/A; Randomized; and Non-randomized

Randomized
Non-randomized

4.3. Outcome Measures

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

Name	Up to 255 characters.
Type	Outcome Measures Type drop down list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

Other

4.4. Statistical Design and Power

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

dd Attachment | Delete Attachment | View Attachment

4.5. Subject Participation Duration

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

4.6. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No

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

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

Required and system enforced if Yes.

Add Attachment | Delete Attachment | View Attachment

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.

ent

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Add Attachments | Delete Attachments | View Attachments

Form supports up to 10 attachments.

Attachments only allowed for CT studies.

Only include attachments requested in opportunity.

Use requested filename. If a specific filename is not requested, use a meaningful filename since the filename will become a bookmark in the assembled application image.

Optional form in Overall component.

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 3/31/2020

The PHS Assignment Request Form will be posted as a separate document in eRA Commons and is not part of the assembled application image. Content is only made available to select agency staff.

Funding Opportunity Number:

Pre-populated from announcement information.

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

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

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

	First Choice	Second Choice	Third Choice
Assign to Awarding Component:			
Do Not Assign to Awarding Component:			

Study Section Assignment Request *(optional)*

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

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

	First Choice	Second Choice	Third Choice
Assign to Study Section: *Only 20 characters allowed*			
Do Not Assign to Study Section: *Only 20 characters allowed*			

PHS Assignment Request Form

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

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

	1	2	3	4	5
Expertise: *Only 40 characters allowed*					

R&R Budget form will NOT be used in the Overall component. NIH will summarize budget information from other components and include the summaries in the assembled application in eRA Commons post submission.

ASSIST: Budget summary information is available using "Preview Application".

Provide DUNS for the organization whose budget is reflected on this form. DUNS is used to differentiate applicant and subaward budgets.

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: **Enter name of Organization:**

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

Use Project when providing data for the budget associated with the component's lead organization.

A. Senior/Key Person

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

Project Role:

Role should reflect the Sr/Key persons role on the specific component.

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

Total Senior/Key Person

If more than 100 Sr/Key, use attachment and enter total funds requested for additional Sr/Key persons.

B. Other Personnel

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

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months 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)

C. Equipment Description

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

Equipment item		Funds Requested ($)

Once equipment data is entered, you will be able to add up to 99 more rows to this section for a total of 100 equipment items.

Additional Equipment: Add Attachment | Delete Attachment | 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

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

		Funds Requested ($)
1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	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.		
9.		
10.		
	Total Other Direct Costs	

Subaward/Consortium/Contractural Costs are not pre-populated. Include both Direct and Indirect 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.

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		
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)		

The actual look of this form will vary based on your submission method. The Grants.gov PDF version is shown here.

ASSIST: Add to your application using "Add Optional Form" available from the Summary tab for the component.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

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

Click here to extract the R&R Subaward Budget Attachment

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

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.

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 Atta				w Attachment
5) Please attach Atta				w Attachment
6) Please attach Atta				w Attachment
7) Please attach Atta				w Attachment
8) Please attach Atta				w 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
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 TRAINING BUDGET, Period 1

Provide DUNS for the organization whose budget is reflected on this form.

Use Project when providing data for the budget associated with the component's lead organization.

Organizational DUNS: Budget Type: ☐ Project ☐ Subaward/Consortium

Organization Name:

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 SF424 (R&R) cover.

Start Date: End Date:

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.

A. Stipends, Tuition/Fees

Number of Trainees: Full Time	Short Term		Stipends Requested ($)	Tuition/Fees Requested ($)
		Undergraduate:		
		Number Per Stipend Level: First-Year/Soph. ☐ Junior/Senior ☐		
		Predoctoral: Single Degree		
		Dual Degree		
		Total Predoctoral		
		Postdoctoral: *Number Per Stipend Level:* 0 1 2 3 4 5 6 7		
		Non-degree Seeking		
		Degree Seeking		
		Total Postdoctoral		
		Other:		
		Totals:		

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

Total Stipends + Tuition/Fees Requested

B. Other Direct Costs

	Funds Requested ($)
Trainee Travel	
Training Related Expenses	Warning if not provided.
Total Direct Costs from R&R Budget Form (if applicable)	Must be manually entered.
Consortium Training Costs (if applicable)	
Total Other Direct Costs Requested	

Include sum of all attached Training Subaward Budget forms.

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.				
			Total Indirect (F&A) Costs Requested	

Indirect Cost Rate is typically 8%.

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

F. Budget Justification

Budget justification is required and must cover all budget periods. Attachment | View Attachment

PHS 398 TRAINING BUDGET, Cumulative Budget

Values automatically 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. The Grants.gov PDF version is shown here.

ASSIST: Add to your application using "Add Optional Form" available from the Summary tab for the component.

OMB Number: 0925-0001
Expiration Date: 3/31/2020

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				View Attachment
Attach Training				View Attachment
Attach Training				View Attachment
Attach Training				View Attachment
Attach Training				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 n 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.

OMB Number: 0925-0001
Expiration Date: 3/31/2020

ASSIST: Add to your application using "Add Optional Form".

PHS Additional Indirect Costs - Budget Period 1

ORGANIZATIONAL DUNS: **Enter name of Organization:**

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

Indirect Costs

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	

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 3/31/2020

Introduction

1. Introduction to Application (for Resubmission and Revision applications) — Limited to 1 page. Overall: Required for resubmission and revision applications. Other components: optional unless otherwise stated in funding opportunity announcement. [Add Attachment] [Delete Attachment] [View Attachment]

Research Plan Section

2. Specific Aims — Required for all components. Limited to 1 page. [Add Attachment] [Delete Attachment] [View Attachment]
3. *Research Strategy — Required for all components. See Section IV of the funding opportunity announcement for Overall and component page limits. Typically 6, 12 or 30 pages.
4. Progress Report Publication List [Add Attachment] [Delete Attachment] [View Attachment]

Other Research Plan Section

5. Vertebrate Animals — Overall: Not collected. Other components: Required 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 — Overall: Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.
8. Consortium/Contractual Arrangements — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement.
9. Letters of Support — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement.
10. Resource Sharing Plan(s) — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement.
11. Authentication of Key Biological and/or Chemical Resources — Overall: Optional unless otherwise stated in FOA. Other components: Required if project involves key biological and/or chemical resources. Recommend 1 page, but no system validation enforcement of page limit.

Appendix

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

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

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

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

PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001
Expiration Date: 3/31/2020

Introduction

1. Introduction to Application (for Resubmission and Revision applications) — Optional for Resubmission and Revision applications. Must not be included for new or renewal applications. Limited to 1 page. — 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 announcement. — 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 announcement.

5. Progress Report Publication List (for Renewal applications) — Optional 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 — Limited to 6 pages. — Add Attachment | Delete Attachment | View Attachment

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s) — Required. Limited to 6 pages. — Add Attachment | Delete Attachment | 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

Other Research Plan Sections

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

13. Select Agent Research — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement.

14. Consortium/Contractual Arrangements — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement.

15. Resource Sharing — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement.

16. Authentication of Key Biological and/or Chemical Resources — Required if component involves key biological and/or chemical resources. No system validation enforcement. — View Attachment

Appendix

17. Appendix

Add A

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

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

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

* Citizenship

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

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

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

☐ With a Permanent U.S. Resident Visa

☐ With a Temporary U.S. Visa

Non-U.S. Citizen national with temporary U.S. Visa' is not typically a valid option.

☐ 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: ☐

PHS 398 Research Training Program Plan

OMB Number: 0925-0001
Expiration Date: 3/31/2020

Introduction

1. Introduction to Application (for Resubmission and Revision applications) — Optional for Resubmission applications; limited to 3 pages. Optional 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 — Rigor & transparency changes for training applications delayed (NOT-OD-16-034). Until further notice, do not use this attachment unless specifically indicated in your funding opportunity announcement. | Add Attachment | Delete Attachment | View Attachment
5. Multiple PD/PI Leadership Plan (if applicable) | Add Attachment | Delete Attachment | View Attachment
6. Progress Report (for Renewal applications) — Optional 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 — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement. | 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. | Add Attachment | Delete Attachment | View Attachment

Other Training Program Section

10. Vertebrate Animals — Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form. | Add Attachment | Delete Attachment | View Attachment
11. Select Agent Research — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement. | Add Attachment | Delete Attachment | View Attachment
12. Consortium/Contractual Arrangements — Can include in Overall, other components, or both unless specific instructions provided in the funding opportunity announcement. | Add Attachment | Delete Attachment | View Attachment

Appendix

13. Appendix | Add Attachments | Delete Attachments | View Attachments

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

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

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