Annotated Form Set for NIH Grant Applications

FORMS-E Series – Application due dates on/after January 25, 2018

Table of Contents

Forms Common to Most Application Packages	**Page #**
SF424 (R&R)	2
PHS 398 Cover Page Supplement	4
R&R Other Project Information	6
Project/Performance Site Location(s)	7
R&R Senior/Key Person Profile (Expanded)	8
SBIR/STTR Information	9
PHS Human Subjects and Clinical Trials Information	11
PHS Assignment Request Form	17
Budget Forms	
PHS Modular Budget	19
R&R Budget	20
R&R Subaward Budget Attachment(s) Form	24
PHS 398 Training Budget	25
Training Subaward Budget Attachment Form	27
PHS Additional Indirect Costs	28
Construction Budget	30
Research Plan and Equivalent Forms	
PHS 398 Research Plan	31
PHS 398 Career Development Award Supplemental Form	32
PHS 398 Research Training Program Plan	34
PHS Fellowship Supplemental Form	35

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 only need to complete the forms provided to you with a specific FOA.
- The actual display of the forms depends on your submission method (ASSIST, system-to-system solution, Workspace). The same form fields and guidance apply regardless of submission method, even if the display is slightly different.
- This resource is for FORMS-E application packages, see Do I Have the Right Forms for My Application?
- Registration in multiple systems is needed prior to submission, see Get Registered! Can take 6 weeks – start early!
- Don't forget to periodically check the Related Notices section of the FOA for any updates to instructions or policies since the opportunity was posted.
- The blue annotations throughout this resource represent tips, processing notes and eRA system business rule checks (i.e., validations).

NIH National Institutes of Health
Office of Extramural Research

APPLICATION FOR FEDERAL ASSISTANCE
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 for a due date (e.g., 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:

Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations. Must be 9 or 13 digits; no letters or special characters.

Must provide zip+4 for all zip codes.

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

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.

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

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:

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:

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

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: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

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

Cell Line(s) (Example: 0004):

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

4. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents: 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

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

Name of former Project Director/Principal Investigator:

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

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

☐ Change of Grantee Institution

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

*Name of former institution:

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

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

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

1.a. If YES to Human Subjects

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

Exemptions 7 and 8 are not currently used.

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 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.

IRB Approval Date:

Human Subject Assurance Number:

If Human Subjects = Yes, the Human Subject Assurance Number or the text 'None' must be provided exactly as it appears in eRA Commons institution profile.

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 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.

IACUC Approval Date:

Animal Welfare Assurance Number:

If Vertebrate Animals = Yes, the Animal Welfare Assurance Number or the text 'None' must be provided. Type the number exactly as it appears in eRA Commons Institution Profile.

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.

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.

11. Equipment

Required unless otherwise noted in opportunity. Limited system enforcement.

12. Other Attachments Add Attachments Delete Attachments View Attachments

Only provide Other Attachments when requested in the funding opportunity announcement text or application guide. 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.

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.

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.

* Street1:

Street2:

* 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/additional-performance-site.htm

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name:
* 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:

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

VALID ERA COMMONS USERNAME MUST BE SUPPLIED. Contact PD/PI must be affiliated in Commons with applicant organization. Commons account designated on this form should not have both the PI and SO roles (if PD/PI also serves as SO, use a separate account for SO functions).

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

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

Degree Type:
Degree Year:

***Attach Biographical Sketch**
Attach Current & Pending Support

Required. Limited to 5 pages. Format page, instructions 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:
* 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:

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

For multiple PD/PI applications, you must use the PD/PI role and provide the eRA Commons username in the Credential field for all PD/PIs. If multiple PD/PIs are included, the Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form is required.

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

Degree Type:
Degree Year:

Attach Biographical Sketch Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

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

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.

To ensure proper per application, close the Adobe Reader, and reopen it.

Form only included in small business funding opportunity announcements.

SBIR/STTR Information

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

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

☐ DOE ☐ HHS ☐ USDA ☐ Other:

Check HHS for all NIH, CDC, and FDA submissions.

*** SBC Control ID:** Required. *(This 9 digit code is obtained from the Small Business Administration)*

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)**

Must select SBIR or STTR (not Both).

☐ SBIR ☐ STTR

☐ Both *(See agency-specific instructions to determ cy allows a single submission for both SBIR and STTR)*

Congressional authority to accept Direct Phase II expired.

Not valid for HHS (NIH, CDC, FDA).

*** Application Type (select only one)**

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

☐ Commercialization Readiness Program *(See agency-specific instructions to determine application type participation.)*

Check opportunity for allowable Application Types.

Congressional authority to accept CRP expired.

Phase I Letter of Intent Number:

Leave blank. N/A for HHS (NIH, CDC, FDA) submissions. Workspace users: Enter 0.

*** Agency Topic/Subtopic:** Optional.

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

☐ 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	* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov Selection required.
☐ 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	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? Selection required.
	* 7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase I/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * 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 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

☐ Yes ☐ No	* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment. * Attach File: Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

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

Questions 10 - 12 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 - 12 blank.

☐ Yes ☐ No	* 10. Please indicate whether the answer to BOTH of the following questions is TRUE: (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND (2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?
☐ Yes ☐ No	* 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?
	* 12. Provide DUNS Number of non-profit research partner for STTR. Enter the DUNS or DUNS+4 number of the non-profit research partner for the STTR applicant.

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

PHS Human Subjects and Clinical Trials Information

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

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

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.

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

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

Add Attachment | Delete Attachment | View Attachment

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 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.

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

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. Exemptions 7 and 8 are not currently used.

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

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

2.2. Eligibility Criteria

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

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

2.3. Age Limits **Minimum Age** Dropdown: Years, Months **Maximum Age** Dropdown: 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.

Dropdown: 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. Dropdown: 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.

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.

Inclusion Enrollment Report

1. * 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. View Attachment

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

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

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

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

Section 4 - Protocol Synopsis

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

4.1. Brief Summary

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

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

4.2.a. Narrative Study Description

Up to 32,000 characters.

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

4.2.c. Interventions Up to 20 Interventions allowed.

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

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

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

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

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

4.2.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

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

4.2.g. Allocation

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

N/A
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	Primary Secondary Other Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

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.

Optional form in most grant application packages.

The PHS Assignment Request Form 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.

The Division of Receipt & Referral (DRR) assigns applications based on the most appropriate match between it, the terms of the FOA, and the mission of each possible awarding component, with your preferences taken into consideration when possible. Watch for typos - automated tools may look for specific strings.

PHS Assignment Request Form

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

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:				If DRR's best match is on your list, then it will go with it, even if not your first choice.
Do Not Assign to Awarding Component:				DRR may still assign to listed IC if they determine it is the best match.

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*				If DRR's best match is on your list, then it will go with it, even if not your first choice.
Do Not Assign to Study Section: *Only 20 characters allowed*				DRR may still assign to listed study section if they determine it is the best match.

PHS Assignment Request Form

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

Provide sufficient information (e.g., name organization affiliation) to correctly identify each individual.
Provide specific reason why an individual should not review your application.

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

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

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

PHS 398 Modular Budget

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

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

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

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:**

Only the primary applicant organization should use Budget Type of Project.

A. Senior/Key Person

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

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

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	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, 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.	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 9 more rows to this section for a total of 10 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. In ASSIST, use the Add Optional Form option to add the R&R Subaward Budget tab to your application.

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.

Do not include the Subaward Budget Attachment form with applications that use the PHS 398 Modular 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 Atta				w Attachment
10) Please attach Att				w 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.

Only the applicant organization should use Project.

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 SF 424 (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

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 ☐		
			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:		

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

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 must be 8 for all Ts.

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

F. Budget Justification

Budget justification is required and must cover all budget periods. 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. In ASSIST, use the Add Optional Form option to add the Training Subaward Budget tab to your application.

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.

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.

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 Subaward Budget 13		Add Attachment	Delete Attachment	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

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

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	

BUDGET INFORMATION - Construction Programs

OMB Approval No. 4040-0008
Expiration Date 01/31/2019

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.

Totals (Columns 1-b) are system verified.

COST CLASSIFICATION	a. Total Cost	b. Costs Not Allowable for Participation	c. Total Allowable Costs (Columns a-b)
1. Administrative and legal expenses	$	$	$ 0.00
2. Land, structures, rights-of-way, appraisals, etc.	$	$	$ 0.00
3. Relocation expenses and payments	$	$	$ 0.00
4. Architectual and engineering fees	$	$	$ 0.00
5. Other architectural and engineering fees	$	$	$ 0.00
6. Project inspection fees	$	$	$ 0.00
7. Site work	$	$	$ 0.00
8. Demolition and removal	$	$	$ 0.00
9. Construction	$	$	$ 0.00
10. Equipment	$	$	$ 0.00
11. Miscellaneous	$	$	$ 0.00
12. SUBTOTAL *(sum of lines 1-11)*	$ 0.00	$ 0.00	$ 0.00
13. Contingencies	$	$	$ 0.00
14. SUBTOTAL	$ 0.00	$ 0.00	$ 0.00
15. Project (program) income	$	$	$ 0.00
16. TOTAL PROJECT COSTS *(subtract #15 from #14)*	$ 0.00	$ 0.00	$ 0.00

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.	$ 0.00

Previous Edition Usable

Authorized for Local Reporoduction

Standard Form 424C (Rev. 7-97)
Prescribed by OMB Circular A-102

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 (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. | Attachment

3. *Research Strategy — Adhere to page limits specified in Application Guide and/or FOA. Typically 6 or 12 pages; a small number of FOAs will specify 30 pages. | Attachment

4. Progress Report Publication List | Add Attachment | Delete Attachment | View 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. | Attachment

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

Appendix

12. Appendix | 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) — Required 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. — ttachment

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) — 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. — ttachment

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. — hment | 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. — nt

13. Select Agent Research — Add Attachment | Delete Attachment | View Attachment

14. Consortium/Contractual Arrangements — Add Attachment | Delete Attachment | View Attachment

15. Resource Sharing — Add Attachment | Delete Attachment | View Attachment

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

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* Citizenship

18. * 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

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

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

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

5. Multiple PD/PI Leadership Plan (if applicable)

Required when multiple Sr/Key entries with the role of PD/PI are included on the R&R Sr/Key Person form.

6. Progress Report (for Renewal applications)

Required for Renewal applications.

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

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.

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PHS Fellowship Supplemental Form

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

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. — Add Attachment | Delete Attachment | View Attachment

Other Research Training Plan Section

Vertebrate Animals

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

Are Vertebrate Animals Used? ☐ Yes ☐ No

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

If "**Yes**" to euthanasia

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

If "**No**" to AVMA guidelines, describe method and provide scientific justification — Up to 1000 characters.

13. Vertebrate Animals — Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form. — Add Attachment | Delete Attachment | View Attachment

PHS Fellowship Supplemental Form

Other Research Training Plan Information

14. Select Agent Research — Add Attachment | Delete Attachment | View Attachment

15. Resource Sharing Plan — Add Attachment | Delete Attachment | View Attachment

16. Authentication of Key Biological and/or Chemical Resources

Rigor & transparency changes for individual fellowship applications delayed (NOT-OD-16-034). Until further notice, do not use this attachment unless specifically indicated in your funding opportunity announcement.

Additional Information Section

17. Human Embryonic Stem Cells

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

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

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

Cell Line(s):

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Add up to 200 cell lines.

18. Alternate Phone Number:

19. Degree Sought During Proposed Award:

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

20. * Field of Training for Current Proposal:

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

21. * Current or Prior Kirschstein-NRSA Support? ☐ Yes ☐ No

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

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

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

22. * Applications for Concurrent Support ☐ Yes ☐ No

If yes, describe in an attached file: Limited to 1 page. — Add Attachment | Delete Attachment | View Attachment

Answer must be No for F05.

23. * Citizenship:

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

Non-U.S.Citizen ☐ With a Permanent U.S. Resident Visa

☐ With a Temporary U.S. Visa

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

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

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

24. ☐ Change of Sponsoring Institution — Name of Former Institution:

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

PHS Fellowship Supplemental Form

Budget Section

All Fellowship Applicants:

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

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

Senior Fellowship Applicants Only:

Fields in this section are required for F33.

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

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

a. Federal Stipend Requested: Amount | Number of Months

b. Supplementation from Other Sources: Amount | Number of Months

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

Source

Appendix

28. Appendix: Add Attachments | Delete Attachments | View Attachments

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