Preview of Grant Application Form Changes (FORMS-F)

February 10, 2020

Grant applications to NIH for due dates on/after May 25, 2020 must use application form packages with a "FORMS-F" Competition ID.

This document summarizes the form updates to be included in FORMS-F application packages.

Summary

Form	Changes	Page
SF424 (R&R)	• Updated Expiration Date	3

PHS 398 Cover Page Supplement	• Updated Expiration Date
	• Added Human Fetal Tissue Section including question - "Does the proposed project involve human fetal tissue obtained from elective abortions?"
	   ○ If Yes, two new attachments are requested
	      1. HFT Compliance Assurance
	      2. HFT Sample IRB Consent Form
	• Renumbered form fields, as needed
		5

R&R Other Project Information	• Updated Expiration Date	7
Project/Performance Site Locations(s)	• Updated Expiration Date	8
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PHS Additional Indirect Costs Form	• Updated Expiration Date	19
SF 424C Budget Information – Construction Programs	• No changes	21
PHS 398 Research Plan	• Updated Expiration Date	22
PHS 398 Career Development Award Supplemental Form	• Updated Expiration Date • Added new attachment titled "Description of Candidate's Contribution to Program Goals" to the Environment and Institutional Commitment to Candidate Section • Renumbered form fields, as needed	23
PHS 398 Research Training Program Plan	• Updated Expiration Date	25
PHS Fellowship Supplemental Form	• Updated Expiration Date • Added new attachment titled "Description of Candidate's Contribution to Program Goals" to the Institutional Environment and Commitment to Training Section • Renumbered form fields, as needed	26

SBIR/STTR Information	• Updated Expiration Date • Added Phase IIC as an Application Type option • Note: "Phase IIC" was added to meet the needs of another federal agency; NIH has no plans to allow this option	29
PHS Human subjects and Clinical Trials Information	• Updated Expiration Date • Reworked landing page to allow an answer and supporting explanation for the question "Does any of the proposed research in the application involve human specimens and/or data?" regardless of answer to human subjects involvement question (previously only available if human subjects involvement was no) **Study record changes** • Defaulted Clinical Trial Questionnaire question "1.4.a Does the study involve human participants?" to Yes, since study records are only available when the answer to the "Are Human Subjects Involved?" question on the R&R Other Project Information form is Yes • Separated "Inclusion of Women, Minorities, and Children" attachment into two attachments – "Inclusion of Individuals Across the Lifespan" and "Inclusion of Women and Minorities" • Renamed "Enrollment of First Subject" field to "Enrollment of First Participant" • Added "Inclusion Enrollment Report Title" field to the Inclusion Enrollment Report • Removed "Brief Summary" attachment • Renamed "Narrative Study Description" attachment to "Detailed Description" • Added new question and checkbox – "Is this an applicable clinical trial under FDAAA?" • Renumbered form fields, as needed	31

PHS Assignment Request Form	• Updated Expiration Date
	• Clarified instruction text displayed on form
	• Changed several field labels
	• Removed fields
	    ○ Do Not Assign to Awarding Components
	    ○ Do Not Assign to Study Sections
	• Added "Rationale for assignment suggestions" text box
		38

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

Updated Expiration Date.

1. TYPE OF SUBMISSION

☐ Pre-application   ☐ Application   ☐ Changed/Corrected Application

2. DATE SUBMITTED	Applicant Identifier

4. a. Federal Identifier

b. Agency Routing Identifier

c. Previous Grants.gov Tracking ID

5. APPLICANT INFORMATION

Organizational DUNS:

Legal Name:

Department: Division:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES   ZIP / Postal Code:

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:

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

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:

☐ 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:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:

Start Date   Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: ____   First Name: [_____]   Middle Name: ____

Last Name: [_____]   Suffix: ____

Position/Title: ____

Organization Name: [_____]

Department: ____   Division: ____

Street1: [_____]

Street2: ____

City: [_____]   County / Parish: ____

State: [_____]   Province: ____

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

Phone Number: [_____]   Fax Number: ____

Email: [_____]

15. ESTIMATED PROJECT FUNDING

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**

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: [_____]

Signature of Authorized Representative   **Date Signed**

[_____]   [_____]

20. Pre-application [_____]   [Add Attachment]   [Delete Attachment]   [View Attachment]

21. Cover Letter Attachment [_____]   [Add Attachment]   [Delete Attachment]   [View Attachment]

PHS 398 Cover Page Supplement

Updated Expiration Date.

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☐ No

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

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)

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):

4. Human Fetal Tissue Section

Added new Human Fetal Tissue Section. Renumbered subsequent form fields.

*Does the proposed project involve human fetal tissue obtained from elective abortions? Yes ☐ No ☐

If "yes" then provide the HFT Compliance Assurance

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

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

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

PHS 398 Cover Page Supplement

5. Inventions and Patents Section (for Renewal applications)

*Inventions and Patents: Yes ☐   No ☐

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

*Previously Reported: Yes ☐   No ☐

6. Change of Investigator/Change of Institution Section

☐ Change of Project Director/Principal Investigator

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

Updated Expiration Date.

1. Are Human Subjects Involved? ☐ Yes ☐ No

  1.a. If YES to Human Subjects

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

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

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

    IRB Approval Date: _____

    Human Subject Assurance Number: _____

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

  2.a. If YES to Vertebrate Animals

    Is the IACUC review Pending? ☐ Yes ☐ No

    IACUC Approval Date: _____

    Animal Welfare Assurance Number: _____

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

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

4.b. If yes, please explain: _____

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: _____

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

5.a. If yes, please explain: _____

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

6.a. If yes, identify countries: _____

6.b. Optional Explanation: _____

7. Project Summary/Abstract _____ [Add Attachment] [Delete Attachment] [View Attachment]

8. Project Narrative _____ [Add Attachment] [Delete Attachment] [View Attachment]

9. Bibliography & References Cited _____ [Add Attachment] [Delete Attachment] [View Attachment]

10. Facilities & Other Resources _____ [Add Attachment] [Delete Attachment] [View Attachment]

11. Equipment _____ [Add Attachment] [Delete Attachment] [View Attachment]

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

Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

Organization Name:

DUNS Number:

* 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:

* 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]

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

Updated Expiration Date.

PROFILE - Project Director/Principal Investigator

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: _____

* **Project Role:** PD/PI   **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]

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: _____

* **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]

[Delete Entry]   [Next Person]

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

ORGANIZATIONAL DUNS: | **Enter name of Organization:** | | Updated Expiration Date.

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

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Cal.	Months Acad.	Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)

Project Role: PD/PI

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 |

B. Other Personnel

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

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 ($)

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

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

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]

RESEARCH & RELATED BUDGET - Cumulative Budget

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) [_____]

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

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

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

Click here to extract the R&R Subaward Budget Attachment

</div>

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

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

PHS 398 Modular Budget

Budget Period: 1	Updated Expiration Date.

Start Date: [   ]   End Date: [   ]

A. Direct Costs

Funds Requested ($)

	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 ($)	Funds Requested ($)

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

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

PHS 398 TRAINING BUDGET, Period 1

Updated Expiration Date.

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

Organization Name: [   ]

Start Date: [   ]   End Date: [   ]

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 [ ]

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

Postdoctoral: Number Per Stipend Level:

Full Time	Short Term		0	1	2	3	4	5	6	7	Stipends Requested ($)	Tuition/Fees Requested ($)
[ ]	[ ]	Non-degree Seeking	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	Degree Seeking	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	**Total Postdoctoral**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	Other:									[ ]	[ ]

	Stipends Requested ($)	Tuition/Fees Requested ($)
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. 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			[ ]

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

[   ]

F. Budget Justification

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

PHS 398 TRAINING BUDGET, Cumulative Budget

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)

TRAINING SUBAWARD BUDGET ATTACHMENT(S) FORM

Updated Expiration Date.

Instructions:

This form allows you to attach a PHS 398 Training Budget form for each subaward/consortium associated with your application. Use the "Click here to extract the PHS 398 Training Subaward Attachment" button to extract a blank copy of the PHS 398 Training Budget form, complete the form in accordance with the agency instructions, and attach the completed form using one of the "Add Attachment" buttons.

[Click here to extract the PHS 398 Training Subaward Attachment]

Important:

Attach Training Subaward Budget forms, using the blocks below. Remember that the files you attach must be
PHS 398 Training Budget PDF forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

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

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 ($)**	**Funds Requested ($)**

Total Indirect Costs

Budget Justification

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

PHS Additional Indirect Costs - Cumulative Budget

Totals ($)

Indirect Costs

No changes.

BUDGET INFORMATION - Construction Programs

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

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

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 [   ] % $ [   ]

PHS 398 Research Plan

Updated Expiration Date.

Introduction

1. Introduction to Application
   (for Resubmission and Revision
   applications)   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

Research Plan Section

2. Specific Aims   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

3. *Research Strategy   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

4. Progress Report Publication List [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

Other Research Plan Section

5. Vertebrate Animals   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

6. Select Agent Research   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

7. Multiple PD/PI Leadership Plan   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

8. Consortium/Contractual Arrangements [ ] [Add Attachment] [Delete Attachment] [View Attachment]

9. Letters of Support   [ ]   [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   [ ]   [Add Attachment] [Delete Attachment] [View Attachment]

Appendix

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

PHS 398 Career Development Award Supplemental Form

Updated Expiration Date.

Introduction

1. Introduction to Application
   (for Resubmission and Revision applications)
   [Add Attachment] [Delete Attachment] [View Attachment]

Candidate Section

2. Candidate Information and Goals for Career Development
   [Add Attachment] [Delete Attachment] [View Attachment]

Research Plan Section

3. Specific Aims
   [Add Attachment] [Delete Attachment] [View Attachment]

4. * Research Strategy
   [Add Attachment] [Delete Attachment] [View Attachment]

5. Progress Report Publication List
   (for Renewal applications)
   [Add Attachment] [Delete Attachment] [View Attachment]

6. Training in the Responsible Conduct of Research
   [Add Attachment] [Delete Attachment] [View Attachment]

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring
   [Add Attachment] [Delete Attachment] [View Attachment]

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s)
   [Add Attachment] [Delete Attachment] [View Attachment]

9. Letters of Support from Collaborators, Contributors, and Consultants
   [Add Attachment] [Delete Attachment] [View Attachment]

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment
    [Add Attachment] [Delete Attachment] [View Attachment]

11. Institutional Commitment to Candidate's Research Career Development
    [Add Attachment] [Delete Attachment] [View Attachment]

12. Description of Candidate's Contribution to Program Goals
    [Add Attachment] [Delete Attachment] [View Attachment]

Added "Description of Candidate's Contribution to Program Goals" attachment. Renumbered subsequent form fields.

Other Research Plan Sections

13. Vertebrate Animals
    [Add Attachment] [Delete Attachment] [View Attachment]

14. Select Agent Research
    [Add Attachment] [Delete Attachment] [View Attachment]

15. Consortium/Contractual Arrangements
    [Add Attachment] [Delete Attachment] [View Attachment]

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

17. Authentication of Key Biological and/or Chemical Resources
    [Add Attachment] [Delete Attachment] [View Attachment]

PHS 398 Career Development Award Supplemental Form

Appendix

18. Appendix

[Add Attachments] [Delete Attachments] [View Attachments]

* Citizenship

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

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

☐ With a Permanent U.S. Resident Visa

☐ With a Temporary U.S. Visa

☐ Not Residing in the U.S.

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

PHS 398 Research Training Program Plan

Updated Expiration Date.

Introduction

1. Introduction to Application
   (for Resubmission and Revision
   applications)
   [ ]   Add Attachment   Delete Attachment   View Attachment

Training Program Section

2. * Program Plan
   [ ]   Add Attachment   Delete Attachment   View Attachment

3. Plan for Instruction in the
   Responsible Conduct of Research
   [ ]   Add Attachment   Delete Attachment   View Attachment

4. Plan for Instruction in Methods
   for Enhancing Reproducibility
   [ ]   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)
   [ ]   Add Attachment   Delete Attachment   View Attachment

Faculty, Trainees and Training Record Section

7. Participating Faculty Biosketches
   [ ]   Add Attachment   Delete Attachment   View Attachment

8. Letters of Support
   [ ]   Add Attachment   Delete Attachment   View Attachment

9. Data Tables
   [ ]   Add Attachment   Delete Attachment   View Attachment

Other Training Program Section

10. Vertebrate Animals
    [ ]   Add Attachment   Delete Attachment   View Attachment

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

PHS Fellowship Supplemental Form

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Updated Expiration Date.

Introduction

1. Introduction to Application
   (for Resubmission applications)
   [Add Attachment] [Delete Attachment] [View Attachment]

Fellowship Applicant Section

2. * Applicant's Background and Goals
   for Fellowship Training
   [Add Attachment] [Delete Attachment] [View Attachment]

Research Training Plan Section

3. * Specific Aims
   [Add Attachment] [Delete Attachment] [View Attachment]

4. * Research Strategy
   [Add Attachment] [Delete Attachment] [View Attachment]

5. * Respective Contributions
   [Add Attachment] [Delete Attachment] [View Attachment]

6. * Selection of Sponsor and Institution
   [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
   [Add Attachment] [Delete Attachment] [View Attachment]

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

9. Sponsor and Co-Sponsor Statements
   [Add Attachment] [Delete Attachment] [View Attachment]

10. Letters of Support from Collaborators,
    Contributors, and Consultants
    [Add Attachment] [Delete Attachment] [View Attachment]

Institutional Environment and Commitment to Training Section

11. Description of Institutional Environment
    and Commitment to Training
    [Add Attachment] [Delete Attachment] [View Attachment]

12. Description of Candidate's
    Contribution to Program Goals

Added "Description of Candidate's Contribution to Program Goals" attachment.
Renumbered subsequent form fields.

[Attachment]

Other Research Training Plan Section

Vertebrate Animals

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

Are Vertebrate Animals Used?   ☐ Yes   ☐ No

13. Are vertebrate animals euthanized?   ☐ Yes   ☐ No

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

14. Vertebrate Animals
    [Add Attachment] [Delete Attachment] [View Attachment]

PHS Fellowship Supplemental Form

Other Research Training Plan Information

15. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
16. Resource Sharing Plan		Add Attachment	Delete Attachment	View Attachment
17. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

Additional Information Section

18. 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):

[   ]

19. Alternate Phone Number: [   ]

20. Degree Sought During Proposed Award:

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

21. * Field of Training for Current Proposal:

[   ]

22. * 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

23. * Applications for Concurrent Support ☐ Yes ☐ No

If yes, describe in an attached file: [   ] Add Attachment Delete Attachment View Attachment

24. * 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

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: ☐

25. ☐ Change of Sponsoring Institution Name of Former Institution:

[   ]

PHS Fellowship Supplemental Form

Budget Section

All Fellowship Applicants:

26. * 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:

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

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

	Amount	Number of Months
a. Federal Stipend Requested:		

	Amount	Number of Months
b. Supplementation from Other Sources:		

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

Source

Appendix

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

SBIR/STTR Information

Updated Expiration Date.

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

☐ DOE   ☐ HHS   ☐ USDA   ☐ Other:

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

* Program Type (select only one)

☐ SBIR   ☐ STTR

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

* Application Type (select only one)

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

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

Added Phase IIC as an Application Type option to meet the needs of another federal agency. NIH has no plans to allow this option.

Phase I Letter of Intent Number: [   ]

* Agency Topic/Subtopic: [   ]

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?
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award. [ ]
☐ Yes ☐ No	*** 1c.** Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms?
☐ Yes ☐ No	*** 1d.** Is your small business a Faculty or Student-Owned entity?
☐ Yes ☐ No	*** 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:
☐ 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
☐ Yes ☐ No	*** 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: [ ] [Add Attachment] [Delete Attachment] [View Attachment]
☐ Yes ☐ No	*** 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:
☐ 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)?
	* 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: [ ] [Add Attachment] [Delete Attachment] [View Attachment]

SBIR/STTR Information

SBIR-Specific Questions:

Questions 8 and 9 apply only to SBIR applications. If you are submitting <u>ONLY</u> 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:

Questions 10 - 12 apply only to STTR applications. If you are submitting <u>ONLY</u> 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. [_____]

PHS Human Subjects and Clinical Trials Information

Use of Human Specimens and/or Data   Made Human Specimens and/or Data Section required for all applications.   Updated Expiration Date.

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

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

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

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?   ☐ Yes   ☐ No

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

Exemption number: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If No to Human Subjects

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 a study name and justification for omission of human subject study information.

Other Requested Information

[   ]   [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)

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

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Updated Expiration Date.

* Always required field

Section 1 - Basic Information

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

1.2. * Is this Study Exempt from Federal Regulations?   ☐ Yes   ☐ No

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

1.4. * Clinical Trial Questionnaire

Defaulted question 1.4.a to Yes, since Study Records are only available when Human Subjects = Yes.

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

1.4.a. Does the study involve human participants?   ☒ Yes   ☐ No

1.4.b. Are the participants prospectively assigned to an intervention?   ☐ Yes   ☐ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?   ☐ Yes   ☐ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?   ☐ Yes   ☐ No

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

2.2. Eligibility Criteria

2.3. Age Limits   **Minimum Age**   **Maximum Age**

2.3.a. Inclusion of Individuals Across the Lifespan

Separated "Inclusion of Women, Minorities, and Children" attachment into two attachments - "Inclusion of Individuals Across the Lifespan" and "Inclusion of Women and Minorities."

2.4. Inclusion of Women and Minorities

2.5. Recruitment and Retention Plan   Add Attachment   Delete Attachment   View Attachment

2.6. Recruitment Status

2.7. Study Timeline   Add Attachment   Delete Attachment   View Attachment

2.8. Enrollment of First Participant

Renamed "Enrollment of First Subject" field to "Enrollment of First Participant."

2.9. Inclusion Enrollment Report(s)

Added field number for Inclusion Enrollment Report(s).

Add Inclusion Enrollment Report

Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Added "Inclusion Enrollment Report Title field. Up to 600 characters. Renumbered subsequent form fields.

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

3. * Enrollment Location Type   ☐ Domestic ☐ Foreign

4. Enrollment Country(ies)

5. Enrollment Location(s)

6. Comments

Planned

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)

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

Report 1 of 1

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects [ ] [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

If yes, describe the single IRB plan [ ] [Add Attachment] [Delete Attachment] [View Attachment]

3.3. Data and Safety Monitoring Plan [ ] [Add Attachment] [Delete Attachment] [View Attachment]

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

[ ] Yes [ ] No

3.5. Overall Structure of the Study Team [ ] [Add Attachment] [Delete Attachment] [View Attachment]

Section 4 - Protocol Synopsis

4.1. Study Design Removed Brief Summary attachment. Renumbered subsequent form fields.

4.1.a. Detailed Description Renamed "Narrative Study Description" attachment to "Detailed Description."

4.1.b. Primary Purpose [ ]

4.1.c. Interventions

Intervention Type	
Name	
Description	

4.1.d. Study Phase [ ]

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

4.1.e. Intervention Model [ ]

4.1.f. Masking [ ] Yes [ ] No

[ ] Participant [ ] Care Provider [ ] Investigator [ ] Outcomes Assessor

4.1.g. Allocation [ ]

4.2. Outcome Measures

Name	
Type	
Time Frame	
Brief Description	

4.3. Statistical Design and Power [   ] [Add Attachment] [Delete Attachment] [View Attachment]

4.4. Subject Participation Duration [   ]

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

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

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

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

4.7. Dissemination Plan [   ] [Add Attachment] [Delete Attachment] [View Attachment]

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments [Add Attachments] [Delete Attachments] [View Attachments]

PHS Assignment Request Form

Updated Expiration Date.

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Suggestions (optional)   Clarified instructions.

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

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

Suggested Awarding Components:

Changed field labels. Removed "Do Not Assign to Awarding Component" fields.

Study Section Assignment Suggestions *(optional)*   Clarified instructions.

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

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

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

Suggested Study Sections:
Only 20 characters allowed

Changed field labels. Removed "Do Not Assign to Study Section" fields.

Rationale for assignment suggestions *(optional)*   Added "Rationale for assignment suggestions" text box.   *Entry is limited to 1000 characters.*

PHS Assignment Request Form

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

[empty text box]

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

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