

# Annotated Form Set for NIH Small Business (SBIR/STTR) Grant Applications

FORMS-G Series – Application due dates on/after January 25, 2022

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### NOTES:

- The Funding Opportunity Announcement (FOA) and the [SBIR/STTR Application Guide instructions](#) are the official documents for application requirements. This resource is meant to complement, not replace, those documents.
  - Periodically check the Related Notices section of the FOA for updates to instructions or policies since the opportunity was posted.
- Blue annotations in this resource represent tips for completing form fields and avoiding common errors/warnings.
- Each [SBIR and STTR Funding Opportunity](#) has its own unique set of forms. Once you have identified an opportunity of interest, you must use a submission system (e.g., ASSIST) to access and prepare the forms.
  - [Preparing Your Application Using ASSIST](#)
- The actual display of the forms depends on your submission method (e.g., ASSIST). The same forms, form fields and guidance apply regardless of submission option even if the display is slightly different.
- Registration in multiple systems required – see [Register Your Company!](#) Can take 6 weeks – start early!
- Learn [How to Apply](#) for NIH small business funding on the [NIH SEED website](#).



# APPLICATION FOR FEDERAL ASSISTANCE SF 424 (R&R)

## 1. TYPE OF SUBMISSION

Use Application for first submission attempt for due date.

Pre-application  Application  Changed/Corrected Application

## 2. DATE SUBMITTED

### Applicant Identifier

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.)

## 5. APPLICANT INFORMATION

Legal Name: [Redacted]

Department: FORMS-G: 100 characters. Division: FORMS-G: 100 characters.

Street1: [Redacted] FORMS-G: Unique Entity Identifier (UEI) replaced DUNS. Same identifier must be used in all registrations and within this field of application. UEIs are 12 alpha-numeric characters.

Street2: [Redacted]

City: [Redacted] County / Parish: [Redacted] State: FORMS-G: Updated state list. Province: [Redacted]

Country: USA: UNITED STATES Small business must be in U.S. or U.S. territory. FORMS-G: Updated country list. ZIP / Postal Code: [Redacted] Must provide zip+4 for all zip codes.

Person to be contacted on matters involving this application

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

Last Name: [Redacted] Suffix: [Redacted]

Position/Title: [Redacted]

Street1: [Redacted]

Street2: [Redacted]

City: [Redacted] County / Parish: [Redacted] State: FORMS-G: Updated state list. Province: [Redacted]

Country: USA: UNITED STATES FORMS-G: Updated country list. ZIP / Postal Code: [Redacted]

Phone Number: [Redacted] Fax Number: [Redacted]

Email: [Redacted] 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):

Small business must be in U.S. or U.S. territory. Must select "R. Small Business" for SBIR/STTR applications.

## 7. TYPE OF APPLICANT:

Other (Specify): [Redacted] Please select one of the following

Small Business Organization Type  Women Owned  Socially and Economically Disadvantaged

## 8. TYPE OF APPLICATION:

New  Resubmission  A. Increase Award  B. Decrease Award  C. Increase Duration  D. Decrease Duration

Renewal  Continuation  Revision  E. Other (specify): [Redacted]

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

## 9. NAME OF FEDERAL AGENCY:

## 10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

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

## 11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

Phase II should have the same title as awarded Phase I. If Revision (box 8), provide exact title (including punctuation and spacing) as seen in eRA Commons for awarded grant. Limited to 200 characters.

## 12. PROPOSED PROJECT:

## 13. CONGRESSIONAL DISTRICT OF APPLICANT

Start Date [Redacted] Ending Date [Redacted] Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). See application guide for additional details.

The funding opportunity provides an "Earliest Project Start Date". For example, the omnibus/parent and other opportunities that use the Sept 5/Jan 5/ April 5 standard due dates have corresponding Earliest Project Start Dates of April/July/September.

Generally, project durations are ... Phase 1: 6-12 months, Fast-Track: 2.5-3 yrs, Phase II: 2 yrs, Phase IIB: up to 3 yrs, Commercialization Readiness Pilot (CRP): up to 3 years.

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:  FORMS-G: Updated state list. Province:   
 Country:  USA: UNITED STATES FORMS-G: Updated country list. 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:  SBIR/STTR: Check "No - Program is not covered by E.O."  
 DATE:   
 b. NO  PROGRAM IS NOT COVERED BY E.O. 12372; OR  
 PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

I agree

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

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

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

19. Authorized Representative

Prefix:  First Name:  Middle Name:   
 Last Name:  Suffix:   
 Position/Title:   
 Organization:   
 Department:  Division:   
 Street1:   
 Street2:   
 City:  County / Parish:   
 State:  FORMS-G: Updated state list. Province:   
 Country:  USA: UNITED STATES FORMS-G: Updated country list. 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. If application proposes the use of human fetal tissue (HFT) from elective abortions, you must include a Cover Letter with a statement about HFT involvement.

# PHS 398 Cover Page Supplement

OMB Number: 0925-0001  
Expiration Date: 09/30/2024

## 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)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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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. Human Fetal Tissue Section

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

If "yes" then provide the HFT Compliance Assurance

Required if Yes. Cannot be included if No.

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

Required if Yes. Cannot be included if No.

# PHS 398 Cover Page Supplement

## 5. Inventions and Patents Section (for Renewal applications)

SBIR/STTR: Only applies to Phase II 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 Investigator not allowed for Revision applications.

Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:

\*First Name:

Middle Name:

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

Suffix:

Change of Grantee Institution

\*Name of former institution:

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

Consider entire project (work done by applicant and subawards).

### RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001  
Expiration Date: 12/31/2022

1. Are Human Subjects Involved?  Yes  No  
Answer Yes if human subjects activities are part of the proposed project at any performance site. If Yes, additional information may be required on the PHS Human Subjects and Clinical Trials Information form.

1.a. If YES to Human Subjects  
Is the Project Exempt from Federal regulations?  Yes  No  
Only answer Yes if all the proposed research human subject studies are exempt.

If yes, check appropriate exemption number.  1  2  3  4  5  6  7  8  
If including multiple study records, enter all exemptions selected across all studies.

If no, is the IRB review Pending?  Yes  No  
IRB Approval Date: \_\_\_\_\_  
IRB Approval Date is not required at time of submission; may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

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

2. Are Vertebrate Animals Used?  Yes  No  
2.a. If YES to Vertebrate Animals  
Answer Yes if vertebrate animals activities are part of the proposed project at any performance site. If Yes, an additional attachment is required on the PHS 398 Research Plan form.

Is the IACUC review Pending?  Yes  No  
IACUC Approval Date: \_\_\_\_\_  
IACUC Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

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

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

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

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

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

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

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

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

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

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

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. Research must be performed in U.S. facilities. Foreign sites must be approved by the funding officer. [View Attachment](#)

11. Equipment  
Required unless otherwise noted in opportunity. Limited system enforcement.

12. Other Attachments [Add Attachments](#) [Delete Attachments](#) [View Attachments](#)

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

### Project/Performance Site Location(s)

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.

**Project/Performance Site Primary Location**

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

UEI:  **← Unique Entity Identifier (UEI) required and enforced by NIH. FORMS-G: UEI replaced DUNS.**

\* Street1:

Street2:

\* City:  County:

\* State:  **FORMS-G: Updated state list.**

Province:

\* Country: USA: UNITED STATES  **FORMS-G: Updated country list.**

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

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

**Project/Performance Site Location 1**

Organization Name:

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

\* Street1:

Street2:

\* City:  County:

\* State:  **FORMS-G: Updated state list.**

Province:

\* Country: USA: UNITED STATES  **FORMS-G: Updated country list.**

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

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

**Additional Location(s)**

**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: <input type="text"/>	* First Name: <input type="text"/>	Middle Name: <input type="text"/>
* Last Name: <input type="text"/>	Suffix: <input type="text"/>	
Position/Title: <input type="text"/>	Department: <input type="text"/>	FORMS-G: 100 characters.
Organization Name: <input type="text"/>	Division: <input type="text"/>	FORMS-G: 100 characters.
* Street1: <input type="text"/>	Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.	
Street2: <input type="text"/>		
* City: <input type="text"/>	County/ Parish: <input type="text"/>	
* State: <input type="text"/>	FORMS-G: Updated state list.	Province: <input type="text"/>
* Country: USA: UNITED STATES	FORMS-G: Updated country list.	* Zip / Postal Code: <input type="text"/>
* Phone Number: <input type="text"/>	Fax Number: <input type="text"/>	
* E-Mail: <input type="text"/>	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).	
Credential, e.g., agency login: <input type="text"/>		
* Project Role: <input type="text"/>	Other Project Role Category: <input type="text"/>	
Degree Type: <input type="text"/>	Project Role will default to PD/PI and must remain PD/PI (do not edit - we string match).	
Degree Year: <input type="text"/>	Required. Limited to 5 pages. Format page, instructions and samples: <a href="http://grants.nih.gov/grants/forms/biosketch.htm">http://grants.nih.gov/grants/forms/biosketch.htm</a>	
* Attach Biographical Sketch <input type="checkbox"/>	<input type="checkbox"/>	attachment
Attach Current & Pending Support <input type="checkbox"/>	<input type="checkbox"/>	attachment
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: <input type="text"/>	* First Name: <input type="text"/>	Middle Name: <input type="text"/>
* Last Name: <input type="text"/>	Suffix: <input type="text"/>	
Position/Title: <input type="text"/>	Department: <input type="text"/>	FORMS-G: 100 characters.
Organization Name: <input type="text"/>	Division: <input type="text"/>	FORMS-G: 100 characters.
* Street1: <input type="text"/>	Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.	
Street2: <input type="text"/>		
* City: <input type="text"/>	County/ Parish: <input type="text"/>	
* State: <input type="text"/>	FORMS-G: Updated state list.	Province: <input type="text"/>
* Country: USA: UNITED STATES	FORMS-G: Updated country list.	* Zip / Postal Code: <input type="text"/>
* Phone Number: <input type="text"/>	Fax Number: <input type="text"/>	
* E-Mail: <input type="text"/>	eRA Commons ID required for everyone listed on this form. If named personnel don't have eRA Commons IDs, the applicant company may choose to create IDs with a "Scientist" or "Project_Personnel" role (Commons functionality limited to maintaining personal profiles).	
Credential, e.g., agency login: <input type="text"/>		
* Project Role: <input type="text"/>	Other Project Role Category: <input type="text"/>	
Degree Type: <input type="text"/>	For multiple PD/PI, you must use the PD/PI role and include a Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form.	
Degree Year: <input type="text"/>	Required. Limited to 5 pages. Format page, instructions and samples: <a href="http://grants.nih.gov/grants/forms/biosketch.htm">http://grants.nih.gov/grants/forms/biosketch.htm</a>	
Attach Biographical Sketch <input type="checkbox"/>	<input type="checkbox"/>	attachment
Attach Current & Pending Support <input type="checkbox"/>	<input type="checkbox"/>	attachment
Only provide Current & Pending Support if specifically requested in FOA. May be requested later in pre-award process as Just-In-Time data.		

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



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

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

OMB Number: 4040-0001  
Expiration Date: 12/31/2022

UEI:  Enter name of Organization:

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

**A. Senior/Key Person**

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

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			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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

STTR: If the PD/PI is an employee of the Research Institution (RI), then their information should be entered on the RI subaward budget page and the amounts on the Project budget can be blank or \$0.

SBIR: There must be a Sr/Key entry with a role of PD/PI for each budget year of the Project budget.

Additional Senior Key Persons:  Add Attachment Delete Attachment View Attachment Total Funds requested for all Senior Key Persons in the attached file

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

Total Senior/Key Person

**B. Other Personnel**

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

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
<input type="text"/>	Post Doctoral Associates	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Graduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Undergraduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Secretarial/Clerical	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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 (\$)
<input type="text" value="Enter up to 10 equipment items."/>	<input type="text"/>

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

Additional Equipment:

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)	<input type="text"/>
2. Foreign Travel Costs <input type="text" value="Generally, Foreign Travel Costs do not apply to SBIR/STTR applications."/>	<input type="text"/>
<b>Total Travel Cost</b>	<input type="text"/>

**E. Participant/Trainee Support Costs**

Funds Requested (\$)

1. Tuition/Fees/Health Insurance	<input type="text"/>
2. Stipends	<input type="text"/>
3. Travel	<input type="text"/>
4. Subsistence	<input type="text"/>
5. Other <input type="text"/>	<input type="text"/>
<input type="text"/> Number of Participants/Trainees	<input type="text"/>
<b>Total Participant/Trainee Support Costs</b>	<input type="text"/>

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

**F. Other Direct Costs**

	Funds Requested (\$)
1. Materials and Supplies	<input type="text"/>
2. Publication Costs	<input type="text"/>
3. Consultant Services	<input type="text"/>
4. ADP/Computer Services	<input type="text"/>
5. Subawards/Consortium/Contractual Costs	<input type="text"/>
6. Equipment or Facility Rental/User Fees	<input type="text"/>
7. Alterations and Renovations	<input type="text"/>
8. <input type="text"/>	<input type="text"/>
9. <input type="text"/>	<input type="text"/>
10. <input type="text"/>	<input type="text"/>
11. <input type="text"/>	<input type="text"/>
12. <input type="text"/>	<input type="text"/>
13. <input type="text"/>	<input type="text"/>
14. <input type="text"/>	<input type="text"/>
15. <input type="text"/>	<input type="text"/>
16. <input type="text"/>	<input type="text"/>
17. <input type="text"/>	<input type="text"/>
<b>Total Other Direct Costs</b>	

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

FORMS-G: Increased number of additional Other Direct Costs line items from 3 to 10.

Examples of possible uses: Tuition Remission; Technical Assistance; Patient Care Costs.

If requesting Technical and Business Assistance (TABAs) funding, you must include a "Technical Assistance" line item in line 8, 9, or 10. See [NOT-OD-21-062](#).

If proposing the use of human fetal tissue from elective abortions, you must include a "Human Fetal Tissue Costs" item (if no cost incurred, enter 0). Type the string as requested (without quotation marks). Systems will only pick up an exact match to the letters and spacing of the string (not case specific). The line item cannot be combined with any "Other" costs.

**G. Direct Costs**

**Total Direct Costs (A thru F)**

**H. Indirect Costs**

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Applicants without a NIH-negotiated Indirect Cost Rate can request up to 40% in both Phase I and Phase II.

**Total Indirect Costs**

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

**I. Total Direct and Indirect Costs**

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

**J. Fee**  A reasonable fee, not to exceed 7% of total costs for each Phase of the project is available with SBIR/STTR awards. A Fee cannot be entered for a Subaward/Consortium budget.

**Funds Requested (\$)**

**K. Total Costs and Fee**

**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 (\$)

<b>Section A, Senior/Key Person</b>		
<b>Section B, Other Personnel</b>		
Total Number Other Personnel		
<b>Total Salary, Wages and Fringe Benefits (A+B)</b>		
<b>Section C, Equipment</b>		
<b>Section D, Travel</b>		
1. Domestic		
2. Foreign		
<b>Section E, Participant/Trainee Support Costs</b>		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
<b>Section F, Other Direct Costs</b>		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
11. Other 4		
12. Other 5		
13. Other 6		
14. Other 7		
15. Other 8		
16. Other 9		
17. Other 10		

FORMS-G: Increased number of additional Other Direct Costs line items from 3 to 10.

**Section G, Direct Costs (A thru F)**

**Section H, Indirect Costs**

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

**Section J, Fee**

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

## R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

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

[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.

1) Please attach Attachment 1	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
2) Please attach Attachment 2	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
3) Please attach Attachment 3	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
4) Please attach Attachment 4	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
5) Please attach Attachment 5	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
6) Please attach Attachment 6	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
7) Please attach Attachment 7	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
8) Please attach Attachment 8	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
9) Please attach Attachment 9	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
10) Please attach Attachment 10	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
11) Please attach Attachment 11	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
12) Please attach Attachment 12	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
13) Please attach Attachment 13	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
14) Please attach Attachment 14	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
15) Please attach Attachment 15	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
16) Please attach Attachment 16	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
17) Please attach Attachment 17	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
18) Please attach Attachment 18	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
19) Please attach Attachment 19	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
20) Please attach Attachment 20	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
21) Please attach Attachment 21	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
22) Please attach Attachment 22	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
23) Please attach Attachment 23	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
24) Please attach Attachment 24	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
25) Please attach Attachment 25	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
26) Please attach Attachment 26	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
27) Please attach Attachment 27	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
28) Please attach Attachment 28	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
29) Please attach Attachment 29	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>
30) Please attach Attachment 30	<input type="text"/>	<a href="#">Add Attachment</a>	<a href="#">Delete Attachment</a>	<a href="#">View Attachment</a>

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.

# PHS 398 Research Plan

OMB Number: 0925-0001  
Expiration Date: 09/30/2024

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	<input type="checkbox"/> Limited to 1 page. Required for Resubmission and Revision applications. <input type="button" value="Attachment"/>
Research Plan Section	
2. Specific Aims	<input type="text"/> Required. Limited to 1 page. <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
3. *Research Strategy	<input type="checkbox"/> Required: Phase I SBIR/STTR: limited to 6 pages. Phase II: SBIR/STTR and Fast Track SBIR/STTR: limited to 12 pages. <input type="button" value="Attachment"/>
4. Progress Report Publication List	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
Other Research Plan Section	
5. Vertebrate Animals	<input type="checkbox"/> Required if Vertebrate Animals is Yes on the Other Project Information form. <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
6. Select Agent Research	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
7. Multiple PD/PI Leadership Plan	<input type="checkbox"/> Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form. <input type="button" value="Attachment"/>
8. Consortium/Contractual Arrangements	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
9. Letters of Support	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
10. Resource Sharing Plan(s)	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
11. Authentication of Key Biological and/or Chemical Resources	<input type="checkbox"/> Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.
Appendix	
12. Appendix	<input type="button" value="Add Attachments"/> <input type="button" value="Delete Attachments"/> <input type="button" value="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.

# SBIR/STTR Information

OMB Number: 4040-0001  
Expiration Date: 12/31/2022

\* 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:

The 9-digit code is included in the registry filename received from SBA upon registration (e.g., SBC\_123456789.pdf.)

\* Program Type (select only one)

SBIR   
  STTR   
 Must select SBIR or STTR (not Both).

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

\* Application Type (select only one)

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

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

Phase I Letter of Intent Number:

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

\* Agency Topic/Subtopic:

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

<input type="checkbox"/> Yes <input type="checkbox"/> 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? <span style="border: 1px solid black; padding: 2px; float: right;">Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).</span>
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award. <span style="border: 1px solid red; padding: 2px; float: right;">Required.</span>
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? <span style="border: 1px solid black; padding: 2px;">Selection required.</span>
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 1d. Is your small business a Faculty or Student-Owned entity? <span style="border: 1px solid black; padding: 2px;">Selection required.</span>
<input type="checkbox"/> Yes <input type="checkbox"/> 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:  <div style="border: 1px solid black; padding: 5px; margin-top: 10px;">                     Required if Yes. Up to 250 characters.                      Cannot include if No.                 </div>
<input type="checkbox"/> Yes <input type="checkbox"/> 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: <a href="http://www.sba.gov">http://www.sba.gov</a> <span style="border: 1px solid black; padding: 2px;">Selection required.</span>
<input type="checkbox"/> Yes <input type="checkbox"/> 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: <input style="border: 1px solid black; padding: 2px;" type="text"/> <span style="border: 1px solid black; padding: 2px; margin-left: 5px;">Required if No. Cannot include if Yes.</span> <span style="border: 1px solid gray; padding: 2px; margin-left: 5px;">Add Attachment</span> <span style="border: 1px solid gray; padding: 2px; margin-left: 5px;">Delete Attachment</span> <span style="border: 1px solid gray; padding: 2px; margin-left: 5px;">View Attachment</span>
<input type="checkbox"/> Yes <input type="checkbox"/> 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:  <div style="border: 1px solid black; padding: 5px; margin-top: 10px;">                     Required if Yes. Up to 250 characters.                      Cannot include if No.                 </div>
<input type="checkbox"/> Yes <input type="checkbox"/> 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)? <span style="border: 1px solid black; padding: 2px;">Selection required.</span>
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 7. Does the application include a request of SBIR or STTR funds for Technical and Business Assistance (TABAs)? If yes, please follow the agency specific instructions to provide the budget request and justification. (Please answer no if you plan to use the agency TABA vendor, which does not require you to include a request for TABA funds in your application.) <span style="border: 1px solid black; padding: 2px; float: right;">FORMS-G: New question.</span>
<input type="checkbox"/> Yes <input type="checkbox"/> No	* 8. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase I/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. <span style="border: 1px solid black; padding: 2px; margin-top: 5px;">Required for Phase II, Direct Phase II, Phase IIB, Phase1/Phase II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.</span>
	* Attach File: <input type="text"/>



## SBIR/STTR Information

### SBIR-Specific Questions:

Answers only required for SBIR applications.

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

<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>* 9. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment.</p> <p>* Attach File: <input style="width: 200px;" type="text"/> <span style="margin-left: 20px;"><input type="button" value="Add Attachment"/></span> <span style="margin-left: 20px;"><input type="button" value="Delete Attachment"/></span> <span style="margin-left: 20px;"><input type="button" value="View Attachment"/></span> </p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>* 10. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?</p>

### STTR-Specific Questions:

Answers only required for STTR applications.

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

<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>* 11. Please indicate whether the answer to BOTH of the following questions is TRUE:</p> <p>(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</p> <p>(2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?</p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>* 12. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?</p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>* 13. Provide UEI of non-profit research partner for STTR.</p> <p><input style="width: 100px;" type="text"/></p> <div style="border: 1px solid black; background-color: #e0ffff; padding: 2px; display: inline-block; margin-top: 5px;"> <b>FORMS-G: Enter the Unique Entity Identifier (UEI) of the non-profit research partner for the STTR applicant.</b> </div>

## PHS Human Subjects and Clinical Trials Information

### Use of Human Specimens and/or Data

\* Does any of the proposed research in the application involve human specimens and/or data?

Yes  No

Answer required for all applications.

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

← Only include attachment if proposed research uses human specimens and/or data not considered to be human subjects research.

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

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

Are Human Subjects Involved?  Yes  No

Is the Project Exempt from Federal regulations?  Yes  No

Exemption number:  1  2  3  4  5  6  7  8

Information populated from R&R Other Project Information form.

### If No to Human Subjects

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

### If Yes to Human Subjects

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

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

### Other Requested Information

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

[Click here to extract the Human Subject Study Record Attachment](#)

### Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

**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
<input type="text"/>	<input type="checkbox"/>	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="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.

HS = Human Subjects  
CT = Clinical Trials

# Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 09/30/2024

\* Always required field

## Section 1 - Basic Information

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

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

### 1.2. \* Is this Study Exempt from Federal Regulations?

Yes  No

Answer required and system enforced.

### 1.3. Exemption Number

1  2  3  4  5  6  7  8

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

### 1.4. \* Clinical Trial Questionnaire

Answers to questionnaire required and system enforced.

1.4.a defaults to Yes and is not editable.

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 exemption 4 is only exemption selected. Up to 20 conditions at 255 characters each.

### 2.2. Eligibility Criteria

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

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

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

### 2.3. Age Limits

Minimum Age

Maximum Age

### 2.3.a. Inclusion of Individuals Across the Lifespan

Required and system enforced unless exemption 4 is only exemption selected.

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

### 2.4. Inclusion of Women and Minorities

Required and system enforced unless exemption 4 is only exemption selected.

### 2.5. Recruitment and Retention Plan

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

### 2.6. Recruitment Status

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

### 2.7. Study Timeline

Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in opportunity.

Attachment View Attachment

### 2.8. Enrollment of First Participant

Date: MM/DD/YYYY.

Dropdown list: Anticipated, Actual

Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset.

### 2.9. Inclusion Enrollment Report(s)

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

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

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

# PHS Inclusion Enrollment Report

1. \* Inclusion Enrollment Report Title

Required. Up to 600 characters.

2. \* Using an Existing Dataset or Resource

Yes  No

Answer required and system enforced.

3. \* Enrollment Location Type

Domestic  Foreign

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

4. Enrollment Country(ies)

Multi-select from list of countries.  
FORMS-G: Updated country selection list.

5. Enrollment Location(s)

6. Comments

Up to 500 characters.

Planned

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

Racial Categories	Ethnic Categories				
	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
<b>Total</b>	0	0	0	0	0

**Cumulative (Actual)**

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

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

**3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?**

Yes  No  N/A

Answer required and system enforced. "N/A" is only a valid option if study is not exempt from federal regulations (i.e., Question 1.2 is No).

**Single IRB plan attachment**

**3.3. Data and Safety Monitoring Plan**

**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**

**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. Study Design**

**4.1.a. Detailed Description**

**4.1.b. Primary Purpose**

**4.1.c. Interventions**

Intervention Type	
Name	<input type="text" value="Up to 200 characters."/>
Description	<input type="text" value="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)

**4.1.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

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

**4.1.g. Allocation**

**4.2. 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.

<b>Name</b>	<span style="border: 1px solid black; padding: 2px;">Up to 255 characters.</span>
<b>Type</b>	<span style="border: 1px solid black; padding: 2px;">Dropdown list: Primary; Secondary; and Other</span>
<b>Time Frame</b>	<span style="border: 1px solid black; padding: 2px;">Up to 255 characters.</span>
<b>Brief Description</b>	<span style="border: 1px solid black; padding: 2px;">Up to 999 characters.</span>

**4.3. Statistical Design and Power**  Required and system enforced for CT study unless otherwise noted in opportunity.

**4.4. Subject Participation Duration**  Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

**4.5. Will the study use an FDA-regulated intervention?**  Yes  No Answer required and system enforced for CT study unless otherwise noted in opportunity.

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

Required and system enforced if Yes.

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

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

**Section 5 - Other Clinical Trial-related Attachments**

**5.1. Other Clinical Trial-related Attachments**

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



# PHS Assignment Request Form

OMB Number: 0925-0001  
Expiration Date: 09/30/2024

Funding Opportunity Number:

Pre-populated from  
announcement information.

Funding Opportunity Title:

## Awarding Component Assignment Suggestions (optional)

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

Information about Awarding Component can be found here: [https://grants.nih.gov/grants/phs\\_assignment\\_information.htm#AwardingComponents](https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents)

Suggested Awarding Components:

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

## Study Section Assignment Suggestions (optional)

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

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

Information about Study Sections can be found here: [https://grants.nih.gov/grants/phs\\_assignment\\_information.htm#StudySection](https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection)

Suggested Study Sections:  
*Only 20 characters allowed*

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

## Rationale for assignment suggestions (optional)

*Entry is limited to 1000 characters.*

Up to 1000 characters.

# PHS Assignment Request Form

List individuals who should not review your application and why *(optional)*

Entry is limited to 1000 characters.

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

Identify scientific areas of expertise needed to review your application *(optional)*

*Note: Do not provide names of individuals*

1

2

3

4

5

Expertise:  
Each entry is limited to 40 characters

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