## Annotated Form Set for NIH Grant Applications: FORMS-I Series

Grant applications to NIH for due dates on/after January 25, 2025 must use application form packages with a "FORMS-I" Competition ID. See <u>High-level Grant Application Form Change Summary: FORMS-I</u> for a list of specific form updates.

Each funding opportunity and associated application package uses a unique subset of the application forms found in this resource. You only need to complete the forms provided to you with a specific funding opportunity.

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#### Notes:

- The funding opportunity, notices in the <u>NIH Guide</u>, and the <u>How to Apply Application Guide</u> define the official application requirements. This resource is meant to complement, not replace, those documents.
- The actual display of the forms depends on your <u>submission option</u> (ASSIST, system-to-system solution, or Workspace). The same form content requirements apply regardless of submission method.
- Organization registration in multiple systems is required prior to submission, see <u>Organization</u> <u>Registrations</u>.

OMB Number: 4040-0001 Expiration Date: 11/30/2025 APPLICATION FOR FEDERAL ASSISTANCE 3. DATE RECEIVED BY STATE State Application Identifier SF 424 (R&R) If New (box 8), leave blank. If Revision/ Use Application for first submission Resubmission/ Renewal (box 8), use 1. TYPE OF SUBMISSION attempt for due date. 4. a. Federal Identifier institute and serial # of previous NIH grant/application # (e.g., CA987654 from Pre-application Application Changed/Corrected Application b. Agency Routing Identifier 1R01CA987654-01). 2. DATE SUBMITTED **Applicant Identifier** For Notices of Special Interest, include Use Changed/Corrected when Do not use Pre-application unless notice number (e.g., NOT-IC-FY-XXX). c. Previous Grants.gov submitting again to Grants.gov indicated in funding opportunity Tracking ID If Changed/Corrected (box 1), provide for a due date (e.g., to correct 5. APPLICANT INFORMATION UEI: previous Grants.gov tracking #. (e.g., eRA identified errors/warnings.) GRANT12345678). Legal Name: Department: Division: 100 characters 100 characters. Street1: Unique Entity Identifier (UEI) replaced DUNS. Same identifier must be used in all registrations and within this field of application. UEIs Street2: are 12 alpha-numeric characters. County / Parish: City: Province: State: Must provide zip+4 for ZIP / Postal Code: Country: USA: UNITED STATES all zip codes. Person to be contacted on matters involving this application Prefix: First Name: Middle Name: Suffix: Last Name: Position/Title Street1: Street2: County / Parish: City: Province: State: Country: ZIP / Postal Code: UNITED STATES Phone Number: Fax Number: Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used. Email: 6. EMPLOYER IDENTIFICATION (EIN) or (TIN): Non-US organizations use 444444444. 7. TYPE OF APPLICANT: Do not use these Small Business Other (Specify): Organization Type checkboxes. **Small Business Organization Type** Women Owned Socially and Economically Disadvantaged 🗲 NIH/CDC/FDA use SAM data to See application 8. TYPE OF APPLICATION: f Revision, mark appropriate box(es). gather this information. guide for definitions. New Resubmission A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration Renewal Continuation Revision E. Other (specify): Is this application being submitted to other agencies? What other Agencies? 9. NAME OF FEDERAL AGENCY: 10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: TITLE: CFDA is also referred to as Assistance Listing Number (ALN). NIH will assign CFDA/ALN post-submission. 11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT: If Revision (box 8), provide exact title (including punctuation and spacing) as provided for awarded grant. Limited to 200 characters. 12. PROPOSED PROJECT: 13. CONGRESSIONAL DISTRICT OF APPLICANT Start Date **Ending Date** Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). Use 00-000 if outside the US. See application guide for additional details See Key Dates section of announcement. Start date is an estimate; typically at least nine months after submission. Project period should not exceed what is allowed in funding opportunity.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION					
Prefix: First Name:	Middle Name:				
Last Name: PD/PI first/last name should match name on Commons ID provided in the Credential field					
Position/Title: R&R Senior/Key Person Profile (Expanded)					
Organization Name:					
Department: Division:					
Street1:					
Street2:					
City: County / Parish:					
State:	Province:				
Country: USA: UNITED STATES	ZIP / Postal Code:				
Phone Number: Fax Number:					
Email:					
15. ESTIMATED PROJECT FUNDING  Manually enter estimated project funding amounts.  16. IS APPLICATION 12372 PROCES	ATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 6S?				
La Total Faderal Funda Daguestad	HIS PREAPPLICATION/APPLICATION WAS MADE VAILABLE TO THE STATE EXECUTIVE ORDER 12372				
	ROCESS FOR REVIEW ON:				
c. Total Federal & Non-Federal Funds	E:				
d. Estimated Program Income	ROGRAM IS NOT COVERED BY E.O. 12372; OR				
P	ROGRAM HAS NOT BEEN SELECTED BY STATE FOR EVIEW				
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, 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.					
*The list of certifications and assurances, or an Internet site where you may obtain this list, is contained  18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentatio	in the announcement or agency specific instructions.				
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18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentatio  Add  19. Authorized Representative  Prefix: First Name:  Last Name:  Position/Title:  Organization:  Department: Division:  Street1:	Attachment  Delete Attachment  View Attachment  Middle Name:  Suffix:  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.				
18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentatio  Add  19. Authorized Representative  Prefix: First Name:  Last Name:  Position/Title:  Organization:  Department: Division:  Street1:  Street2:	Attachment  Delete Attachment  View Attachment  Middle Name:  Suffix:  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				
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18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentatio  Add  19. Authorized Representative  Prefix: First Name:  Last Name:  Position/Title:  Organization:  Department: Division:  Street1:  Street2:  City: County / Parish:  State:  Country: USA: UNITED STATES  Phone Number: Fax Number:  Email:	Attachment  Delete Attachment  Wiew Attachment  Middle Name:  Suffix:  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).  Province:  ZIP / Postal Code:				

# **PHS 398 Cover Page Supplement**

OMB Number: 0925-0001 Expiration Date: 12/31/2027

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 <b>"No"</b> to AVMA guidelines, describe method and provide scientific justification			quired if euthanasia is NOT consistent with delines. Up to 1000 characters.
2. *Program Income Section			
*Is program income anticipated during the periods f	or which the gr	ant support is	requested?
Yes No			
If you checked "yes" above (indicating that program source(s). Otherwise, leave this section blank.	income is anti	cipated), then	use the format below to reflect the amount and
*Budget Period *Anticipated Amount (\$)			*Source(s)
Form accommodates up to 10 budg	Up to 150 ch		f program income budget periods
must be less than or equal to the nu			
	stem cells?		Yes No  ation number of the specific cell line(s) from the following list:
https://grants.nih.gov/stem_cells/registry/current.htm. that one from the registry will be used:	Or, if a specifi	c stem cell lin	e cannot be referenced at this time, check the box indicating
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 emb https://grants.nih.gov/stem_ NIH Registration Number (e	cells/registry/	current.htm a	at time of submission. Use
4. Human Fetal Tissue Section			
*Does the proposed project involve human fetal tissue	obtained from	elective abort	ions? Yes No No
If "yes" then provide the HFT Compliance Assurance			
Required if Yes. Cannot be included if No	O. Add Attachm	Delete At	tachment View Attachment
If "yes" then provide the HFT Sample IRB Consent Fo	orm		
Required if Yes. Cannot be included if No	O. Add Attachm	Delete At	tachment View Attachment

# **PHS 398 Cover Page Supplement**

5. Inventions and Patents Section (for Renewal applications)
*Inventions and Patents: Yes No No
If "Yes" then answer the following:
*Previously Reported: Yes No No
6. Change of Investigator/Change of Recipient Organization Section
Change of Project Director/Principal Investigator  Change of PD/PI is not allowed for Revision or Career  Development (K) applications.
Name of former Project Director/Principal Investigator:
Prefix:
*First Name:
Middle Name:
*Last Name: If change of PD/PI box is checked, you must provide the last name of the former PD/PI.
Suffix:
Change of Recipient Organization Change of Recipient Institution is not allowed for Institution Training grant applications.
*Name of former organization:
If change of Recipient Institution box is checked, you must provide the name of former institution.

RESEARCH & RELATED Other Project Information OMB Number: 4040-0001
If Human Subjects = Yes, additional information may be required
on the PHS Human Subjects and Clinical Trials Information form.  1. Are Human Subjects Involved?  Only answer Yes if all the proposed research.
1.a. If YES to Human Subjects  Only answer Yes if all the proposed research human subject studies are exempt.
Is the Project Exempt from Federal regulations? Yes No If multiple study records are included, enter all
If yes, check appropriate exemption number.
If no, is the IRB review Pending? Yes No IRB Approval Date is not required at time of submission, but may be
requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.
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.a. If YES to Vertebrate Animals  If Vertebrate Animals = Yes, additional attachments are required in the PHS 398 Research Plan or equivalent form.
Is the IACUC review Pending? Yes No IACUC Approval Date is not required at time of submission, but may be requested
IACUC Approval Date:   later in the pre-award process as Just-In-Time data. Date cannot be in the future.
If Vertebrate Animals = Yes, enter the text 'None' or the Office of Laboratory Animal Welfar
(OLAVV)-approved Ammai Wellare 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?
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. Justification" as an Other Attachment in item #12.
Supplied project summary of proposed work. Typically 20 lines or less; system will give error if ever 1
7. Project Summary/Abstract page. If awarded this information becomes public. Do not include proprietary or confidential information.
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. It View Attachment
10. Facilities & Other Resources Required unless otherwise noted in opportunity. Limited system enforcement. V Attachment
11. Equipment Required unless otherwise noted in opportunity. Limited system enforcement.
12. Other Attachments Add Attachments Delete Attachments View Attachments
Only provide Other Attachments when requested in the funding opportunity, notice of
special interest, or application guide. If provided, follow any guidance regarding
attachment filenames.
Field accommodates multiple attachments.

OMB Number: 4040-0010 Expiration Date: 11/30/2025

## **Project/Performance Site Location(s)**

Project/Performance \$			ndividual, and not on behalf of a company, state, or other type of organization.
Organization Name:	DO NOT che	ck box. NIH only a	ccepts applications from registered organizations.
UEI:	Unique Entity Identifier (UEI) re	equired and enforce	ed by NIH.
* Street1:			
Street2:			
* City:		County:	
* State:			
Province:			
* Country: USA: UN	NITED STATES		
* ZIP / Postal Code:		* Project/ Perfo	ormance Site Congressional District:
Project/Performance Organization Name:  UEI:  * Street1:  Street2:  * City:  * State:  Province:  * Country: USA: UN	Optional for non-primary sites. Helps facil application processing, so include if you h	ernment, academia,	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.
* ZIP / Postal Code:		* Project/ Perfo	ormance Site Congressional District:
sites over	commodates up to 300 sites. Use the Addition of the commodates of	mat page at: https:/	//grants.nih.gov/grants-

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

# RESEARCH & RELATED Senior/Key Person Profile (Expanded)

	PROFILE - Pr	oject Director/Principal Inve	stigator				
Prefix: * First	Name:		Middle	Name:			
* Last Name:				Suffix:			
Position/Title:		Departmen	t: 100	characters.			
Organization Name:				Division:	100 characte	rs.	
		ed by NIH for all Sr/Key en nine potential review confli					
Street2:	a by Mill stall to deter	Time potential review comin	cts of lifter	<del> </del>	J		
* City:		County/ Parish:					
* State:			Province:				
* Country: USA: UNITED STATE		TIVE ERA COMMONS USI		stal Code:	DLIED Cambre	t DD/DL may at	
* Phone Number:		RA Commons with applican					
* E-Mail:	the PI and SC	roles (if PD/PI also serves	as SO, us	se a separate a	account for SO	functions).	
Credential, e.g., agency login:		st be associated with PD/F applications. Recommende		nmons Person	al Profile of Fel	owship and (	Career
* Project Role: PD/PI		ult to PD/PI and must rema	-	lo not edit - we	string match)		
Degree Type:	Troject Role Will delate	dictor Bh rana mascrema	III	io not call we	String materi).		
Degree Year:		ired. Limited to 5 pages. F				aakatab	
*Attach Biographical Sketch		//grants.nih.gov/grants-pro	-киаспіп <del>іс</del> пі	Delete Attac	view /	Macriment	
Attach Current & Pending Su		ide Current & Pending Sup ty. May be requested later				ment	
	оррогия	ty. May be requested later	in pre awa		oust iii Tiille ut	ita.	
	PRO	DFILE - Senior/Key Person 1					$\neg$
Prefix: * Firs	t Name:		Middle	Name:			$\neg$
* Last Name:				Suffix:			
Position/Title:		Departmen	t: 100	characters.			
Organization Name:			<u> </u>	Division:		naracters.	
* Street1:		quired by NIH for all Sr/Ke etermine potential review of			n is		
Street2:	used by Mili stall to d	eterriirie poteritiai review o	Offilicts Of	interest.			
* City:		County/ Parish:					
* State:			Province:				
* Country: USA: UNITED STATE	ls		] * Zip / Po	stal Code:			
* Phone Number:	Fax	Number:					
		or all Sr/Key entries (includ					
		terest. For multiple PD/PIs and include a Multiple PD/					
* Project Role:		Other Project Role Category	ory:				
Degree Type:							
Degree Year:		quired. Limited to 5 pages.					
Attach Biographical Sketch		s://grants.nih.gov/grants-pi	Autachment	Delete Attac	mment view /	Attacriment	
Attach Current & Pending Su		y provide Current & Pendir ortunity. May be requested					
Delete Entry			_		Nex	rt Person	
Can collect data for 100 Sr/Key	personnel (including F	PD/PI). Option to provide a	tachment	for additional S	r/Key info is av	ailable after t	he

NIH Office of Extramural Research

forms-directory/additional-senior-key-person-profile-format.

100 entries are made. See Additional Senior/Key Person Profiles format page at: https://grants.nih.gov/grants-process/write-application/

D&D Budget fo	orm must be use	od if the applied	ation requests >¢°	PEOK in any hudge	at pariod is sub	mitted by	o forc	vian inci	titution (	or proposes the	o use of human fotal ties	ue from elective abortions.
					et periou, is sub	Tillited by	a lore	eigii iiisi	ululion, (	or proposes the	e use of flufflatt letal tiss	ue nom elective abortions.
Provide 12 alpha-numeric character Unique Entity Identifier (UEI) for the organization whose budget is reflected on this form.  RESEARCH & RELATED BUDGET - Budget Period 1							OMB Number: 4040-0001 Expiration Date: 11/30/2025					
	UEI:		Ente	r name of Organ	ization:							
Budget Type:	Project		ard/Consortium ary applicant orga	nization should u		et Perio			t Date:		End Date:	<u> </u>
A. Senior/Ke	y Person		ct (unless multi-pr								ole effort in either Calend and Summer Months.	ar
			asurable effort in					lonths 4		Requested	Fringe	Funds
Prefix	First	Middle	Last	Suffix	Base Salary	(\$)	Cai.	Acad. \$	Sum.	Salary (\$)	Benefits (\$)	Requested (\$)
					<b></b>							
Project Role					Base Salary							
			I for the PD/PI (en act string match to		submission,	out is req	uirea p	prior to	award.			
	erva	WIII IOOK IOI EX	act string materit							<b>■ Total Funds</b>	requested for all Senior	
Additional Senio	or Key Persons:	lack	•	Add Atta	Delete	e Attachme	ent \	√iew Atta	achment		sons in the attached file	
			r/Key (100 for mu		ions), use attac	hment ar	nd ente	er total	funds		otal Senior/Key Person	
3. Other Pers		-	dditional Sr/Key pe									
5. Other Pers	Aggre	gate information	on should be provi	ded in section B a	and explained in	Budget	Justific	cation.				
Number of	Project	Polo				Months				uested	Fringe	Funds
Personnel	•				Cal.	Acad.	Sur	n. ──	Sal	ary (\$)	Benefits (\$)	Requested (\$)
	Post Doctoral						<u> </u>	_				
	Graduate Stu						]					
	Undergraduat	e Students										
	Secretarial/Cl	erical										
											will have the option to	
	add anothe	er. If you run ou	ıt of additional cat	egories combine o	categories in a s	single rov	v and e	explain	what wa	is included in t	he Budget Justification.	
	Total Number	Other Personne	I								Total Other Personnel	
							Tot	tal Sal	ary, Wa	ages and Fri	nge Benefits (A+B)	

### C. Equipment Description List items and dollar amount for each item exceeding \$5,000 Funds Requested (\$) **Equipment item** If more than 10 Equipment items (100 for multi-project applications), use attachment and enter total funds requested for additional equipment. **Additional Equipment:** View Attachment Total funds requested for all equipment listed in the attached file **Total Equipment** D. Travel Funds Requested (\$) Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions) Foreign Travel Costs **Total Travel Cost** E. Participant/Trainee Support Costs Funds Requested (\$) Tuition/Fees/Health Insurance Only complete this section if requested to do so in the funding opportunity. Stipends Travel Subsistence 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		Subaward/Consortium/Contractural
5. Subawards/Consortium/Contractual Costs	<del></del>	Costs are not pre-populated. Include
6. Equipment or Facility Rental/User Fees		both Direct and Indirect costs.
7. Alterations and Renovations		
8.		
9. Up to 10 additional Other Direct Costs line items can be added. Examples of possible uses: Tuition F Technical Assistance, and Patient Care Costs.	Remission,	
10		
11. FORMS-H: If a Data Management and Sharing (DMS) plan is included, you must include a "Data Ma		
and Sharing Costs" line item covering DMS costs, including personnel costs (e.g., personnel who wild data for the project). If no cost incurred, enter 0. Type the string as requested (without quotation mark		
not combine the line item with any "Other" costs.	no) und do	
14.		
15. If proposing the use of human fetal tissue from elective abortions, you must include a "Human Fetal Costs" item (if no cost incurred, enter 0). Type the string as requested (without quotation marks) and		
combine the line item with any "Other" costs.		
17.		
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 Indinest Costs		
Cognizant Federal Agency		
(Agency Name, POC Name, and POC Phone Number)		
I. Total Direct and Indirect Costs	· · · · · · · · · · · · · · · · ·	
Total Direct and Indirect Costs  Total Direct and Indirect Institutional Costs (G + H)	Funds Requested (\$)	
J. Fee	Funds Requested (\$)	
K. Total Costs and Fee	Funds Requested (\$)	
Total Costs and Fee (I + J)	(4)	
L. Budget Justification		
(Only attach one file.)  Add Attachment  Delete Attachme	nt View Attachment	
Budget Justification is required and must cover all budget periods.		
If a Data Management and Objection (DMO) also in a label of the control of the co	Assessment and Object	
If a Data Management and Sharing (DMS) plan is included, you must include a section titled "Data N Justification" that provides a brief brief summary of DMS activities and justification for their costs.	vianagement and Sharing	

### **RESEARCH & RELATED BUDGET - Cumulative Budget**

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

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

Section G, Direct Costs (A thru F)	
Section H, Indirect Costs	
Section I, Total Direct and Indirect Costs (G + H)	
Section J, Fee	
Section K, Total Costs and Fee (I + J)	

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

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

## 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	Add Attachment	Delete Attachment	Viev	w Attachment				
2) Please attach Attachment 2	Add Attachment Delete Attachment View							
3) Please attach Attachment 3 Add Attachment Delete Attachment View								
4) Please attach Atta 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/								
5) Please attach Atta Contractual Costs of the parent budget.								
6) Please attach Atta								
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								
8) Please attach Atta K of the R&R Budget form. This form show	uld only be used in conjunct	ion with the R&R Budg	get	v Attachment				
9) Please attach Atta				v Attachment				
10) Please attach Att Do not include the Subaward Budget Atta	chment form with applicatio	ns that use the PHS 3	98	v Attachment				
11) Please attach Att Modular Budget form.	, , , , , , , , , , , , , , , , , , ,	Doloto / titaommont	V.01	v Attachment				
12) Please attach Attachment 12	Add Attachment	Delete Attachment		v Attachment				
13) Please attach Attachment 13	Add Attachment	Delete Attachment	Viev	v Attachment				
14) Please attach Attachment 14	Add Attachment	Delete Attachment	Viev	v Attachment				
15) Please attach Attachment 15	Add Attachment	Delete Attachment	Viev	w Attachment				
16) Please attach Attachment 16	Add Attachment	Delete Attachment	Viev	w Attachment				
17) Please attach Attachment 17	Add Attachment	Delete Attachment	Viev	w Attachment				
18) Please attach Attachment 18	Add Attachment	Delete Attachment	Viev	w Attachment				
19) Please attach Attachment 19	Add Attachment	Delete Attachment	Viev	w Attachment				
20) Please attach Attachment 20	Add Attachment	Delete Attachment	Viev	w Attachment				
21) Please attach Attachment 21	Add Attachment	Delete Attachment	Viev	w Attachment				
22) Please attach Attachment 22	Add Attachment	Delete Attachment	Viev	w Attachment				
23) Please attach Attachment 23	Add Attachment	Delete Attachment	Viev	w Attachment				
24) Please attach Attachment 24	Add Attachment	Delete Attachment	Viev	w Attachment				
25) Please attach Attachment 25	Add Attachment	Delete Attachment	Viev	w Attachment				
26) Please attach Attachment 26	Add Attachment	Delete Attachment	Viev	w Attachment				
27) Please attach Attachment 27	Add Attachment	Delete Attachment	Viev	w Attachment				
28) Please attach Attachment 28	Add Attachment	Delete Attachment	Viev	w Attachment				
29) Please attach Attachment 29	Add Attachment	Delete Attachment	Viev	w Attachment				
30) Please attach Attachment 30	Add Attachment	Delete Attachment	Viev	w Attachment				

The PHS 398 Modular Budget form cannot be used if the application requests >\$250K in direct costs in any budget period, is submitted by a foreign institution, or proposes the use of human fetal tissue from elective abortions.

# PHS 398 Modular Budget

OMB Number: 0925-0001 Expiration Date: 12/31/2027

	Budget Period:	Form allows for up to 5 Budget Periods.
Start Date:	End Date:	
		Funds Requested (\$)
A. Direct Costs  Direct costs requested must be \$250K or le	ess per period to	Direct Cost less Consortium Indirect (F&A)
use Modular Budget form. Request in "mod		Consortium Indirect (F&A)
Some grant programs have limits on Total	Direct Costs. Check annour	ncement. Total Direct Costs 0.00
B. Indirect (F&A) Costs Indirect (F&A) Ty	pe	Indirect (F&A) Indirect (F&A) Rate (%) Base (\$) Funds Requested (\$)
Form allows for up to for four F&A entries.		
Cognizant Agency (Agency Name, POC Name and	Phone Number)	
Indirect (F&A) Rate Agreement Date		Total Indirect (F&A) Costs
C. Total Direct and Indirect (F&A) Costs	s (A + B)	Funds Requested (\$) 0.00
	Cumulative Budget	Information System calculated.
1. Total Costs, Entire Project Perio	d	
Section A, Total Direct Cost less Consor	tium Indirect (F&A) for Entire P	Project Period \$ 0.00
Section A, Total Consortium Indirect (F&	A) for Entire Project Period	\$
Section A, Total Direct Costs for Entire F	Project Period	\$ 0.00
Section B, Total Indirect (F&A) Costs for	Entire Project Period	\$
Section C, Total Direct and Indirect (F&A	•	
Cocker of Total Broad and manded (I al	ly cools (xx 2) for Emilion region	
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
	If a Data Management	t and Sharing (DMS) plan is included, you must provide this
	attachment and include	e a section titled "Data Management and Sharing Justification" rief summary of DMS activities and justification for their costs.

### PHS 398 TRAINING BUDGET, Period 1

OMB Number: 0925-0001 Expiration Date: 12/31/2027

Provide 12 alpha-numeric cha organization whose budget is			JEI) for the		Only the applicant organiz	zation should use Project.
UEI:	V	Budget Type:	Project		Subaward/Consortium	
Organization Name:					end date for each budget p jet start date and less than	period must be later than the
Start Date:		End Date:	K	proje	ect end date listed on the S	F 424 (R&R) cover.
A. Stipends, Tuition	/Feessta	art date listed o	n the SF 424	(R&R)	ns, the first budget period scover. The start date in sub	start date must match the psequent periods must be
Number of Trainees		eater than or ed information for			on the cover. Stipends	Tuition/Fees
Full Short Time Term	Traine	es is NOT provi	ded for T34		Requested (\$)	Requested (\$)
	applications and if it IS provided for T15, Undergraduate: T32 or T35 applications.					
Number Per Stipend Level:						
First-Year/	First-Year/Soph. Junior/Senior					
Predoctoral:	Single Degree	_				
	Dual Degree		ny Predoctor			
	Total Predoct	nrai	toral informat I for T34.	ion is		
Postdoctoral:	-	Number Per Stipe 2 3 4	nd Level: 5 6	7		
Non-degree Seeking						
Degree						
Seeking  Total						
Postdoctoral	<i>ı</i>					
Other: If Nun	nber of Trainees	data is provided	d then	>		
	sponding Stipend be provided and v		ata must	otals:		
	- F		Stipends +	Tuitio	n/Fees Requested	
B. Other Direct Cost	s					Funds Requested (\$)
Trainee Travel						
Training Related Expe	enses					Warning if not provided.
Total Direct Costs from	m R&R Budget F	orm (if applicab	le)	ido oum	of all attached Training	Must be manually entered.
Consortium Training (	Costs (if applicab	le)			Budget forms.	<del>&gt;</del>
			Total Other	r Direc	t Costs Requested	
C. Total Direct Costs	s Requested	(A + B)				
D. Indirect (F&A) Co	sts		Indirect	(F&A)	Indirect (F&A)	Funds
Indire	ct (F&A) Type		Rate	` '	Base	Requested (\$)
1.		Indirect Cost	Pate			
2.		must be 8 for				
<b>4</b> .			Tatal		(EQA) Coots Beauty	
			ı otal İn	iairect	(F&A) Costs Requeste	<b>2</b> 0
E. Total Direct and I	ndirect (F&A)	Costs Requ	uested (C	+ D)		
E Dudmat In-Alfi- u	lan -	Dudget in C	ification in the	u iro d	nd must sover all budget	oriodo
F. Budget Justificati	ION	Duaget justi	incation is rec	luirea a	nd must cover all budget p	eriods. View Attachment

## PHS 398 TRAINING BUDGET, Cumulative Budget

Values are system calculated.

		Stipends Requested (\$)	Tuition/Fees Requested (\$)
Undergraduate	e: [		
Predoctoral:	Single Degree		
	Dual Degree		
	Total Predoctoral		
Postdoctoral:	Non-Degree Seeking		
	Degree Seeking		
	Total Postdoctoral		
Other:			
	Totals:		
. Other Direct  Trainee Trave	l		Funds Requested (\$
Trainee Trave Training Relat	l ed Expenses		
Trainee Trave Training Relat Total Direct Co	l ed Expenses osts from R&R Budget Form (if applicabl	le)	
Trainee Trave Training Relat Total Direct Co	l ed Expenses osts from R&R Budget Form (if applicabl aining Costs (if applicable)		
Trainee Trave Training Relat Total Direct Co Consortium Tr	ed Expenses  osts from R&R Budget Form (if applicable)  aining Costs (if applicable)  Total Other	le)  Direct Costs Requested	
Trainee Trave Training Relat Total Direct Co Consortium Tr	l ed Expenses osts from R&R Budget Form (if applicabl aining Costs (if applicable)		
Trainee Trave Training Relat Total Direct Consortium Tr	ed Expenses  osts from R&R Budget Form (if applicable)  aining Costs (if applicable)  Total Other		

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

TRAINING SUBAWARD BUDGET ATTACHMENT(S) FORM

#### **Instructions:**

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

Click here to extract the PHS 398 Training Subaward Attachment

#### **Important:**

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

Attach Training Subaward Budget 1	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 2	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 3	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 4	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 5	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 6	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 7	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 8	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 9	Add Attachment	Delete Attachment	View Attachment
Attach Training Subaward Budget 10	Add Attachment	Delete Attachment	View Attachment
Attach Training Su The sum of all training subaward budget forms (e.g., those a			View Attachment
Attach Training Sulthose provided as part of the budget justification), must be included in the Consortium Training Costs field in the Other Direct Costs (Section B) of the PHS 398 Training Budget form.			
ttach Training Supaward Budget 13			
Attach Training Sulf submitting an application with >30 subaward budgets, bud to PDF and included as part of the Budget Justification of the	lgets 31 and above e parent budget in	should be converte Section F of the PH	S /iew Attachment
Attach Training Su 398 Training Budget form.			/iew 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

OMB Number: 0925-0001

Expiration Date: 12/31/2027

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

OMB Number: 0925-0001 Expiration Date: 12/31/2027

#### PHS Additional Indirect Costs - Budget Period 1

Provide the 1	2 alpha-numer	ic character Unique	Entity Identifier for th	e applicant organi	zation.				
	UEI:	lacksquare	Enter name	of Organization:					
Budget Type:	Project	Subaward/Con	nsortium	Budge	Period: 1	* Start	Date:	* End Date:	
Indirect Cos	sts								
Indirect Cos	st Type				Indirect Cost	Rate (%)	Indirect Cost Base (\$	) Funds Re	quested (\$)
<u>-</u>			ne costs associated	· ·					
subaward o	rganizations in	the same entry if th	e same indirect cost	rate applies.			Total Indirect Cos	ts	
Budget Just	tification								
Only attach one f	ile.)			Add Attachment	Delete Atta	achment	View Attachment	]	
The Budget	luctification ch	ould explain what is	included in the includ	ded indirect cost in	oformation				

NIH Office of Extramural Research

## PHS Additional Indirect Costs - Cumulative Budget

	Totals (\$)
	System calculated.
Indirect Costs	

OMB Number: 4040-0008 Expiration Date: 11/30/2025

## **BUDGET INFORMATION - Construction Programs**

COST CLASSIFICATION	a. Total Cost	b. Costs Not Allowable for Participation	c. Total Allowable Costs	tal Allowable Cost
Administrative and legal expenses	\$	\$	(Co	olumns a-b) are stem verified.
2. Land, structures, rights-of-way, appraisals, etc.	\$	\$	\$	
Relocation expenses and payments	\$	\$	\$	
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 FUNDI	NG		
17. Federal assistance requested, calculate as follows: (Consult Federal agency for Federal percentage share Enter the resulting Federal share.	are.) Enter eligible costs from line		\$	

# PHS 398 Research Plan

OMB Number: 0925-0001 Expiration Date: 12/31/2027

Introduction				
Introduction to Application (for Resubmission and Revision applications)	Limited to 1 page (except R25 Resubmission can be 3 pages). Required for Resubmission and Revision applications.			
Research Plan Section				
2. Specific Aims	Required (except DP1, DP2, DP4, R35, R50 and X02). Limited to 1 page.			
3. *Research Strategy	Adhere to page limits specified in Application Guide and/or funding opportunity.  Typically 6 or 12 pages; a small number of funding opportunities specify 30 pages.			
4. Progress Report Publication List	Only allowed for Renewals and Resubmissions of Renewals.  Attachment			
Other Research Plan Section				
5. Vertebrate Animals	Required for all apps. (except S10), if Vertebrate Animals is Yes on the Other Project Information form.			
6. Select Agent Research	Add Attachment Delete Attachment View Attachment			
7. Multiple PD/PI Leadership Plan	Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.			
8. Consortium/Contractual Arrangements	Add Attachment Delete Attachment View Attachment			
9. Letters of Support	Required for R36 applications. dd Attachment Delete Attachment View Attachment			
10. Resource Sharing Plan(s)	Add Attachment Delete Attachment View Attachment			
11. Other Plan(s)	Include a Data Management and Sharing (DMS) Plan, if required. See Application Guide and funding opportunity. Recommended <= 2 pages. Typically not part of application image.			
<ol> <li>Authentication of Key Biological and/or Chemical Resources</li> </ol>	used for peer review; posted as separate document in eRA Commons.			
Chemical Resources	Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.			
Appendix				
13. Appendix DO NOT use Appendix a	attachments to circumvent page limits in other sections of			
the application. Applicati	ons will be withdrawn and not reviewed if they are			
	material that are not specifically listed in notice NOT- g opportunity as allowed or required.			
Allows for up to 10 apperestrictions.	endices. See Application Guide and funding opportunity for			
	eparately in the eRA Commons (not as part of the accessible to appropriate agency staff and peer			

# PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001 Expiration Date: 12/31/2027

Introduction				
Introduction to Application     (for Resubmission and Revision applications)	Required for Resubmission and Revision for New or Renewal applications. Limited		ust not be include	Attachment /
Candidate Section				
Candidate Information and Goals for Career Development	Required. This attachment and the Rese a combined total of 12 pages unless other			
Research Plan Section				
3. Specific Aims	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment
4. * Research Strategy	This attachment and the Candidate Informare limited to a combined total of 12 page			
5. Progress Report Publication List (for Renewal applications)		Add Attachment	Delete Attachment	View Attachment
Training in the Responsible Conduct of Research	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment
Other Candidate Information Se	ction			
7. Candidate's Plan to Provide Mentoring	Required for K05 and K24. Do not include K25, K76, K99, K99/R00. Limited to 6 pages		08, K18, K22, K2	tachment
Mentor, Co-Mentor, Consultant,	Collaborators Section			
Plans and Statements of Mentor and Co- Mentor(s)	Required for K01, K08, K18, K23, K25, K if not included for K07 or K22. Limited to	(76, K99, K99/R0 6 pages.	00. Warning	View Attachment
Letters of Support from Collaborators, Contributors, and Consultants	Limited to 6 pages.	Add Attachment	Delete Attachment	View Attachment
Environment and Institutional C	ommitment to Candidate Section			
10. Description of Institutional Environment	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment
Institutional Commitment to Candidate's     Research Career Development	Required. Limited to 1 page.	Add Attachment	Delete Attachment	View Attachment
12. Description of Candidate's Contribution to Program Goals	Required for diversity-related funding op	oportunities only.	Delete Attachment	View Attachment
Other Research Plan Sections				
Other Research Flan Sections				
13. Vertebrate Animals	Required if Vertebrate Animals Used is `	Yes on the R&R	Other Project Info	ormation form.
14. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
15. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
16. Resource Sharing	A Data Management and Sharing (DMS)	Plan required if	research will gen	erate scientific
17. Other Plan(s)	and/or large-scale genomic data. Recom application image used for peer review; p	mended <= 2 pa	ges. Typically no	t part of
18. Authentication of Key Biological and/or Chemical Resources	Required if project involves key biological No system validation enforcement.	I and/or chemica	resources. nent	View Attachment

PHS 398 Career Development Award Supplemental Form DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the funding **Appendix** opportunity as allowed or required. 19. Appendix Allows for up to 10 appendices. See Application Guide and funding opportunity for restrictions. Appendices are stored separately in the eRA Commons (not as part of the application \* Citizenship image) and are accessible to appropriate agency staff and peer reviewers. 20. \* U.S. Citizen or Non-Citizen National? Yes Not allowed for K43. If no, you must select the single, most appropriate Non-U.S. Citizen option. If no, select most appropriate Non-U.S. Citizen option With a Permanent U.S. Resident Visa Not allowed for K43. Non-U.S. Citizen national with temporary U.S. Visa' is With a Temporary U.S. Visa Not allowed for K43. not typically a valid option, though it may be accepted for K99/R00 applications. Not Residing in the U.S. If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here:

# PHS 398 Research Training Program Plan

OMB Number: 0925-0001 Expiration Date: 12/31/2027

Introduction				
Introduction     Introduction to Application     (for Resubmission and Revision applications)	Required for Resubmission applications; limited to 3 pages. Required for Revision applications; limited to 1 page.  View Attachment			
Training Program Section				
2. * Program Plan	Required. Limited to 25 pages.  Add Attachment  Delete Attachment  View Attachment			
Recruitment Plan to Enhance Diversity	Required. Limited to 3 pages.  Add Attachment  Delete Attachment  View Attachment			
Plan for Instruction in the     Responsible Conduct of Research	Required. Limited to 3 pages.  Add Attachment  Delete Attachment  View Attachment			
Plan for Instruction in Methods for Enhancing Reproducibility	Required for institutional career development (K12, KL2, KM1) applications and institutional training (D43, Ts). Limited to 3 pages.			
Multiple PD/PI Leadership Plan     (if applicable)	Required when multiple Sr/Key entries with the role of PD/PI are included on the R&R Sr/Key Person form.			
7. Progress Report (for Renewal applications)	Required for Renewal applications. Limited to 5 pages for a program overview and 1 page for each appointee to the grant.			
Faculty, Trainees and Training Red	cord Section			
8. Participating Faculty Biosketches	Warning if not included.  Add Attachment  Delete Attachment  View Attachment			
9. Letters of Support	Add Attachment Delete Attachment View Attachment			
10. Data Tables	Warning if not included. User defined bookmarks in this attachment are included with the bookmarks in the submitted application image in eRA Commons.			
Other Training Program Section				
11. Vertebrate Animals	Required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.			
12. Select Agent Research	Add Attachment Delete Attachment View Attachment			
13. Consortium/Contractual Arrangements	Add Attachment Delete Attachment View Attachment			
14. Other Plan(s)	NIH Data Sharing Policies are not applicable to institutional training applications. Attachment added for potential future use with other plans.			
Appendix				
15. Appendix Add Attachments	Delete Attachments View Attachments			
	tachments to circumvent page limits in other sections of			
	ns will be withdrawn and not reviewed if they are naterial that are not specifically listed in notice NOT-			

OD-17-098 or the funding opportunity as allowed or required.

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

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

# **PHS Fellowship Supplemental Form**

OMB Number: 0925-0001 Expiration Date: 12/31/2027

Introduction		
Introduction		
Introduction to Application     (for Resubmission applications)	Required for Resubmission applications. Lim	Delete Attachment View Attachment
Candidate Section		
2. * Goals, Preparedness, and Potential	Required. Limited to 3 pages.	Add Attachment Delete Attachment View Attachment
, , , , ,		
Research Training Plan		
3. * Training Activities and Timeline	Required. Limited to 3 pages.	Add Attachment Delete Attachment View Attachment
4. * Research Training Project Specific Aims	Required. Limited to 1 page.	Add Attachment Delete Attachment View Attachment
5. * Research Training Project Strategy	Required. Limited to 6 pages.	Add Attachment Delete Attachment View Attachment
Progress Report Publication List     (for Renewal applications)		Add Attachment Delete Attachment View Attachment
7. * Training in the Responsible Conduct of Research	Required. Limited to 1 page.	Add Attachment Delete Attachment View Attachment
		·
Operation and the Operation of Management		
Commitment to Candidate, Mentoring		
8. Sponsor(s) Commitment	Limited to 6 pages.	Add Attachment Delete Attachment View Attachment
Letters of Support from Collaborators,     Contributors, and Consultants	Limited to 6 pages.	Add Attachment Delete Attachment View Attachment
Description of Candidate's Contribution to Program Goals	Required for diversity-related funding oppor	tunity only. Limited to 2 pages. ht View Attachment
Other Because Training Blan Section		
Other Research Training Plan Section	:1	
Vertebrate Animals		
The fellowing items is taken from the D		A
be made on the Research & Related 0	Research & Related Other Project Information form and repeat Other Project Information form.	ated here for your reference. Any change to this item must
	Are Vertebrate Animals Used?	No
11. Are vertebrate animals euthanized?		ebrate Animals Used is Yes on the R&R
	Other Project Information	on form.
If "Yes" to euthanasia	terinera Madical	
Is method consistent with American Vete Association (AVMA) guidelines?	erinary Medical Yes No	
If "No" to AVMA guidelines, describe metho	od and provide	
scientific justification	Up to 1000 characters.	]
		1
12. Vertebrate Animals	Required if Vertebrate Animals Used is Y	es on the R&R Other Project Information form.

# PHS Fellowship Supplemental Form

Other Research Training Plan Informa	ntion
13. Select Agent Research	Add Attachment Delete Attachment View Attachment
14. Resource Sharing Plan	Add Attachment Delete Attachment View Attachment
15. Other Plan(s)	NIH Data Sharing Policies are not applicable to fellowship applications.  Attachment added for potential future use with other plans.
16. Authentication of Key Biological and/or Chemical Resources	Do not use this attachment unless specifically indicated in your funding opportunity.
One mount of the second of the	
Additional Information Section	
17. Human Embryonic Stem Cells	
* Does the proposed project involve human e	mbryonic stem cells? No
	yonic stem cells, list below the registration number of the specific cell line(s) from the following list: rent.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that
Specific stem or	ell line cannot be referenced at this time. One from the registry will be used.
Cell Line(s):	
Error if provide	ed human embryonic stem cell lines are not listed at
	nih.gov/stem_cells/registry/current.htm at time of Jse NIH Registration Number (e.g., 0004, 0005).
Add up to 200	cell lines.
18. Alternate Phone Number:	
19. Degree Sought During Proposed Award:	
Degree:	If "other", indicate Expected Completion Date degree type: (MM/YYYY):
	Reset Entry
20. * Field of Training for Current Proposal:	
Enter appropriate 3-digit co	ode from drop-down list.
21. * Current or Prior Kirschstein-NRSA Suppo	
If yes, identify current and prior Kirschstei	in-NRSA support below:
* Level * Type	Start Date (if known) End Date (if known) Grant Number (if known)
	required if 'Current Or Prior Kirschstein-NRSA Support' is Yes.
Can provide up to 4 s	support itoms
	support items.
22. * Applications for Concurrent Support	Yes No
22. * Applications for Concurrent Support  If yes, describe in an attached file:	Yes No  Limited to 1 page.  Add Attachment Delete Attachment View Attachment
If yes, describe in an attached file: 23. * Citizenship:	Yes No  Limited to 1 page.  Answer must be No for F05.
If yes, describe in an attached file:  23. * Citizenship:  U.S. Citizen or Non-	Yes No  Limited to 1 page.  Answer must be No for F05.  Answer must meet citizenship
If yes, describe in an attached file: 23. * Citizenship:	Limited to 1 page.  Answer must be No for F05.  Citizen National?  With a Permanent U.S. Resident Visa  Applicants must meet citizenship requirements at time of award (not time of application submission.)
If yes, describe in an attached file:  23. * Citizenship:  U.S.Citizen  U.S. Citizen or Non-  Non-U.S.Citizen  Non-U.S. Citizen with to U.S. Visa only required	Yes

# PHS Fellowship Supplemental Form

24. Change of Sponsoring Instit	Name	e of Former Institution:			
		Required if 'Change of Sponsoring Institution' box is checked.			
Budget Section					
All Fellowship Applicants:					
All I ellowship Applicants.					
25. * Tuition and Fees:	None Requested	Funds Requested:			
_		Year 1			
		Year 2			
		Year 3			
		Year 4			
		Year 5			
		Year 6 (when applicable)			
		Total Funds Requested:			
26. * Childcare Costs:	None Requested	Funds Requested:			
		Year 1			
Applicants can request u	n to \$3000	Year 2			
per year (NOT-OD-24-11		Year 3			
, ,	,	Year 4			
		Year 5			
		Year 6 (when applicable)			
		Total Funds Requested:			
Senior Fellowship Applicants Only	<i>/:</i>				
Fields in this section are re	equired for F33.	Amount Academic Period Number of Months			
27. Present Institutional Base Salary:		Reset Entry			
28. Stipends/Salary During First Y	oar of Proposed Follo	webip:			
20. Superius/Salary During First 1	ear of Froposed Felic	Amount Number of Months			
a. Federal Stipend Requested	l:				
		Amount Number of Months			
b. Supplementation from Othe	er Sources:				
		Type (e.g., sabbatical leave, salary)			
		Type (eig.) substitution said of said.			
		Source			
Appendix					
29. Appendix	Add Attachm	pents Delete Attachments View Attachments			
	T use Annendix	attachments to circumvent page limits in other sections of			
		ions 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 fundi	ng opportunity as allowed or required.			
Allows	for up to 10 appe	endices. See Application Guide and funding opportunity for			
restricti					
		separately in the eRA Commons (not as part of the			
application image) and are accessible to appropriate agency staff and peer reviewers.					

Form only included in small business funding opportunities.

# **SBIR/STTR Information**

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

* Agency to which you are applying (select only one)
DOE HHS USDA Other: Check HHS for all NIH, CDC, and FDA submissions.
* SBC Control ID: Required. The 9-digit code is included in the registry filename received from SBA upon registration (e.g., SBC_123456789.pdf.)
* Program Type (select only one)
SBIR STTR Must select SBIR or STTR (not Both).
Both (See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)  SBIR only (if allowed in Not valid for HHS
* Application Type (select only one) funding opportunity). (NIH, CDC, FDA).
Phase I Phase II Fast-Track Direct Phase II Phase IIA Phase IIB Phase IIC
Commercialization Readiness Program (See agency-specific instructions to determine application type participation.)  Check funding opportunity for allowable Application Types.
Phase I Letter of Intent Number: Leave blank. N/A for HHS (NIH, CDC, FDA) submissions.  Workspace users: Enter 0.
* Agency Topic/Subtopic: Optional.
Questions 1-8 must be completed by all SBIR and STTR Applicants:
Yes No  * 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?  Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).
* 1b. Anticipated Number of personnel to be employed at your organization at the time of award.  Required.
Yes * 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms?
Ves Ves
No Selection required.
Yes * 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:
Selection   required.   Required if Yes. Up to 250 characters.
Cannot include if No.
Yes * 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  No Selection required.
Yes * 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.  Selection * Explanation: Required if No. Cannot include if Yes. Add Attachment Delete Attachment View Attachment
Selection * Explanation: Required if No. Cannot include if Yes. Add Attachment Delete Attachment View Attachme
No Federal program solicitations or received other Federal awards for essentially equivalent work?
Selection * If yes, insert the names of the other Federal agencies: required.
Required if Yes. Up to 250 characters.
Cannot include if No.
Yes  * 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
Selection state-level economic development organizations that may be interested in contacting you for further information (e.g., possible
required.   collaborations, investment)?  Yes   * 7. Does the application include a request of SBIR or STTR funds for Technical and Business Assistance (TABA)? If yes, please follow
the agency specific instructions to provide the budget request and justification. (Please answer no if you plan to use the agency TABA vendor, which does not require you to include a request for TABA funds in your application.)
* 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. Required for Phase II, Direct Phase II, Phase IIB, Phase II Fast-Track and
* Attach File: Commercialization Readiness Program applications. Limited to 12 pages.

# **SBIR/STTR Information**

	Answers only required for SBIR applications.						
SBIR-Specific Questions:  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 questio	on 11.						
Yes No	* 9. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment.						
	* Attach File: Add Attachment Delete Attachment View Attachment						
Yes	* 10. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?						
☐ No							
STTR-S	Answers only required for STTR applications.						
Questions 11 - 13 apply only to STTR applications. If you are submitting <u>ONLY</u> an SBIR application, leave questions 11 - 13 blank.							
Yes	* 11. Please indicate whether the answer to BOTH of the following questions is TRUE:						
No	(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	institution named in the application perform at least 30% of the work?						
	* 13. Provide UEI of non-profit research partner for STTR.						
	Enter the Unique Entity Identifier (UEI) of the non-profit research partner for the STTR applicant.						

## **PHS Human Subjects and Clinical Trials Information**

OMB Number: 0925-0001 Expiration Date: 12/31/2027

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  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.  Anticipated Clinical Trial?  Required and system enforced for each delayed	Use of Human Specimens a	nd/or Data								
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 ferris you are required to complete on this form.  Are Human Subjects and Clinical Trials Information?  Yes No Information populated from R&R Other Project Information form.  If You to Human Subjects  Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.  If Yes to Human Subjects  Skip the rest of the PHS Human Subject Study by selecting "And New Study" or "And New Delayed Onset Study as appropriate. Delayed Onset Studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  Click here to extract the Human Subject Study Record Attachment  Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subject question on R&R Other Project Information form.  Pelayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Multiple delayed onset studyies are project information form.						ired for all				
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 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?  Is the Project Exempt from Federal regulations?	Provide an explanation for	any use of human sp	ecimens and/or data no	t considered	to be hu	man subjec	ts research.			
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?  Is the Project Exempt from Federal regulations?  If No to Human Subject  Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.  If Yes to Human Subjects  Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.  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 Study information.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  1) Please attach Human Subject Study 1  Click here to extract the Human Subject Study if you answer No to human subject squestion on Rand and Delayed Onset Study (les)  Rand Add Attachment Delete Attachment View Attachment Study Title  Cannot add a Delayed Onset Study if you answer No to human subject squestion on Rand Study Information on set studies can be grouped in a single record.  Rand Title Add Attachment Delete Attachment View Attachment Trial?  Add Attachment Delete Attachment View Attachment Trial?	<del></del>		· · · · · · · · · · · · · · · · · · ·	posed res	earch i	uses hum	nan specimens an	d/or data not cons	idered to be	
Are Human Subjects Involved?  Is the Project Exempt from Federal regulations?  If No to Human Subjects and Clinical Trials Information Form.  If Yes 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 Study requested Information attachment when specifically requested in the funding opportunity text or application guide.  Click here to extract the Human Subject Study if you answer No to human subject squestion on R&R Other Project Information form.  Cannot add a Delayed Onset Study if you answer No to human subject squestion on R&R Other Project Information form.  Pelayed Onset Study(ies)  R&R Other Project Information form.  Anticipated Clinical Trial?  Add Attachment Delete Attachment View Attachment Studies can be grouped in a single record.  Anticipated Clinical Trial?  Anticipated Clinical Trial?  Anticipated Required and system enforced for each delayed	Please complete the human subj	ects section of the Re	esearch & Related Othe	r Project Info	rmation f	orm prior to	completing this form.			
Is the Project Exempt from Federal regulations?										
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 movement at the time of submission, per agency policies on Delayed Onset Study in Formation.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  Click here to extract the Human Subject Study Record Attachment  Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  Required and system enforced for each delayed  Required and system enforced for each delayed	Are Human Subjects Involved?			<u> </u>	⁄es	☐ No				
If No to Human Subjects  Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.  If Yes to Human Subjects  Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).  Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  It is a subject study records using unique filenames.  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  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ie.e.) delayed start). Multiple delayed onset studies can be grouped in a single record.  Study Title  Anticipated Clinical Trial?  Anticipated Clinical Trial?		Is the Project Exempt from Federal regulation			⁄es	☐ No				
Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.  If Yes to Human Subjects  Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).  Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  Click here to extract the Human Subject Study Record Attachment  Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Add Attachment  Delete Attachment  View Attachment  Delayed Onset Study (i.e., delayed start), Multiple delayed onset studies can be grouped in a single record.  Study Title  Anticipated Clinical Trial?  Required and system enforced for each delayed		Exemption number:		1	2 [	3 🗌 4	5 6 7	8		
Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).  Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  Click here to extract the Human Subject Study Record Attachment  Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  Pleayed onset Study (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.  Anticipated Clinical Trial?  Justification  Required and system enforced for each delayed	If No to Human Subjects								<u> </u>	
Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.  Other Requested Information  Only provide an Other Requested Information attachment when specifically requested in the funding opportunity text or application guide.  Click here to extract the Human Subject Study Record Attachment  Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  Required and system enforced for each delayed  Add Attachment  Justification  Justification  Justification  Justification  View Attachment  View Attachment  Justification  Anticipated  Clinical  Trial?  Add Attachment  Justification  Justification	Skip the rest of the PHS I	Human Subjects and	Clinical Trials Information	on Form.						
Study Record(s)  Attach human Subject Study records using unique filenames.  Click here to extract the Human Subject Study if you answer No to human subjects question on Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Clanot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Study Title  Add Attachment Justification Trial?  Add Attachment Justification Trial?  Add Attachment Justification Delayed Onset Study for each delayed Add Attachment Justification Justification Trial?	If Yes to Human Subjects			•	•		•			
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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  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  Delayed Onset Study (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.  Study Title  Anticipated Clinical Trial?  Anticipated Clinical Trial?  Required and system enforced for each delayed	Other Requested Informatio	n Only provid	de an Other Reque	ested Infor	mation	attachm	ent when			
Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.  Anticipated Clinical Trial?  Required and system enforced for each delayed	•	specifically	requested in the f	unding op	portuni	ty text or	application guide	nt nt		
Study Record(s)  Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.  Anticipated Clinical Trial?  Required and system enforced for each delayed										
Attach human subject study records using unique filenames.  1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  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?  Required and system enforced for each delayed		Click here to	extract the Human	Subject Stu	idy Reco	ord Attach	ment			
1) Please attach Human Subject Study 1  Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  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.  Anticipated Clinical Trial?  Required and system enforced for each delayed	, (,									
Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.  Delayed Onset Study(ies)  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.  Anticipated Clinical Trial?  Required and system enforced for each delayed	Attach human subject study record	ds using unique filena	mes.							
Delayed Onset Study(ies)  answer No to human subjects question on R&R Other Project Information form.  but will not start immediately (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.  Anticipated Clinical Trial?  Required and system enforced for each delayed	1) Please attach Human Sub					1	Add Attachment	Delete Attachment	View Attachment	
Study Title  Clinical Trial?  Justification  Required and system enforced for each delayed	answer No to human subjects que			stion on	but w	II not sta	rt immediately (i.e	., delayed start). N		
		Study Title		Clinic	Clinical		Jus	Justification		
	7			ا ہا			K			
jonset study. Up to 600 characters. Study title must	Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150					Add Attachment Delete Attachment View Attachment			v Attachment	
characters of title will show in application bookmark. Required and system enforced for each delayed										
If Anticipated Clinical Trial box is checked, funding opportunity must allow clinical trials.  When multiple studies are included in the same delayed onset record, select Yes if it is  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	If Anticipated Clinical Tria funding opportunity must When multiple studies and delayed onset record, sel			allow clini e included lect Yes if	ical tria I in the it is	ls. same	include informat comply with the Board (sIRB) po study, as well as	ion regarding how NIH single Institut licy prior to initiatin s, a plan for the dis	the study will ional Review ng any multi-site ssemination of	
	anticipated that any study w				clinica	trial.		cal trial informatio		

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

HS = Human Subjects CT = Clinical Trials

#### Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 Expiration Date: 12/31/2027 \* 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. Answer required and system enforced. No Yes 1.2. \* Is this Study Exempt from Federal Regulations? If Study Exempt is Yes, must provide 1 2 3 4 5 6 7 8 1.3. Exemption Number exemption number. Exemption must also be selected on Other Project 1.4. \* Clinical Trial Questionnaire Answers to questionnaire required and system enforced. Information form. 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. If four questions are Yes ☐ No 1.4.a. Does the study involve human participants? all Yes AND funding Yes No 1.4.b. Are the participants prospectively assigned to an intervention? opportunity allows Yes No 1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? clinical trials, then No 1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes study will be flagged as a Clinical Trial 1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable (CT) study. 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. Required and system enforced unless Dropdown list: Years, exemption 4 is only exemption selected or 2.2. Eligibility Criteria Dropdown list: Years, Months, Weeks, Days, otherwise noted in funding opportunity. Months, Weeks, Days, Hours, Minutes, N/A Required and system enforced unless exemption 4 is only Hours, Minutes, N/A (No limit) exemption selected or otherwise noted in funding opportunity. (No limit) 2.3. Age Limits Minimum Age Maximum Age Required and system enforced unless exemption 4 is only 2.3.a. Inclusion of Individuals Across the Lifespan exemption selected. If "N/A (No Limit)" Required and system enforced unless exemption 4 is only selected, do not 2.4. Inclusion of Women and Minorities exemption selected. provide numerical min/ Required and system enforced unless exemption 4 is the only 2.5. Recruitment and Retention Plan max age. exemption selected or otherwise noted in funding opportunity. Required and system enforced unless exemption 4 is the only 2.6. Recruitment Status exemption selected or otherwise noted in funding opportunity. View Attachment 2.7. Study Timeline Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in funding opportunity. 2.8. Enrollment of First Participant Enrollment of First Participant field is required and Dropdown list: system enforced unless exemption 4 is only Date: MM/DD/YYYY. Anticipated, exemption selected or using existing dataset. Actual 2.9. Inclusion Enrollment Report(s) Inclusion Enrollment Reports required and system Add Inclusion Enrollment Report enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity. 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.

OMB Number: 0925-0770 Expiration Date: 11/30/2027

# **PHS Inclusion Enrollment Report**

1. " inclusion Enrollment Report Title	
Required. Up to 600 characters.	
2. * Using an Existing Dataset or Resource	
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.	n
4. Enrollment Country(ies)	
Multi-select from list of countries.	
5. Enrollment Location(s)	
6. Comments	
Up to 500 characters.	

#### **Planned**

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

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

#### **Cumulative (Actual)**

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

	Ethnic Categories									
	Not I	Hispanic or La	atino	His	Hispanic or Latino			Unknown/Not Reported Ethnicity		
Racial Categories	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	(
Asian	0	0	0	0	0	0	0	0	0	(
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	(
Black or African American	0	0	0	0	0	0	0	0	0	(
White	0	0	0	0	0	0	0	0	0	(
More than One Race	0	0	0	0	0	0	0	0	0	(
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	(
Total	0	0	0	0	0	0	0	0	0	(

Report 1 of 1

Section 3 - Protection and Monitoring Plans						
3.1. Protection of Human Subje	cts	Required and system e	enforced.	Add Attachment	Delete Attachment	View Attachment
3.2. Is this a multi-site study tha	− <sub>N/Δ</sub> Ans	same protocol to conduct no swer required and system e eral regulations (i.e., Quest	nforced. "N/A" is			
Single IRB plan attachment	:	NIH: If Yes, not require AHRQ: If Yes, required		Add Attachment	Delete Attachment	View Attachment
3.3. Data and Safety Monitoring	Plan	Required and system e	nforced for CT s	tudy. Optional fo	or HS study. ent	View Attachment
ot ot	nswer require herwise noted	d and system enforced for of the distribution			Dalata Attacharant	Visco Attacherent
3.5. Overall Structure of the Stu	dy Team	Optional.		Add Attachment	Delete Attachment	View Attachment
Section 4 - Protocol Synopsis		allowed to complete fields in w clinical trials and/or you a				
4.1. Study Design 4.1.a. Detailed Description						
Up to 32,000 charac		down list: Treatment; Preve	ntion: Diagnosti	ce: Supportive C	aro: Serooning:	
4.1.b. Primary Purpose		th Services Research; Basi				
4.1.c. Interventions Up	to 20 Interver	tions allowed.	(includi	ng sham); Biolog	cluding placebo); gical/Vaccine; Pro	
Intervention Typ		200 characters.	Psycho	r; Radiation; Beh therapy, Lifestyl ng gene transfer	e Counseling); Ge	enetic
Description		,000 characters.	recomb		Dietary Supplem	nent
4.1.d. Study Phase		wn list: Early Phase 1 (or P 2; Phase 2/3; Phase 3; Pha		1; Phase 1/2;		
Is	this an NIH-d	efined Phase III clinical trial?	Yes	No No		
4.1.e. Intervention Model		wn list: Single Group; Paral il; Sequential; and Other	el; Cross-Over;			
4.1.f. Masking	Yes Participant	No Care Provider	Investigator [	Outcomes Asse	must selection the Participer Provider/Ir Outcomes	nvestigator/ Assessor
4.1.g. Allocation	Dropdo	wn list: N/A; Randomized; a	nd Non-randomi	zed	check box	es.

4.2. Outcome Measures

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

	Name	Up to 255 characters.
	Туре	Dropdown list: Primary; Secondary; and Other
	Time Frame	Up to 255 characters.
	Brief Description	Up to 999 characters.
4.3. Sta	atistical Design and Power	Required and system enforced for CT study unless otherwise noted in funding opportunity.  Delete Attachment  View Attachment
4.4. Su	bject Participation Duration	Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in funding opportunity.
4.5	•	Answer required and system enforced for CT study unless otherwise noted in funding opportunity.  Answer required and system enforced for CT study unless otherwise noted in funding opportunity.
De	evice Exemption (IDE) status	Required and system enforced if Yes. Add Attachment Delete Attachment View Attachment
4.6. Is	this an applicable clinical trial	under FDAAA?
4.7. Dis	ssemination 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.
Sectio	n 5 - Other Clinical Trial-related	d Attachments
5.1. Oth	ner Clinical Trial-related Attach	ments Add Attachments Delete Attachments View Attachments

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

## **PHS Assignment Request Form**

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

#### **Awarding Component Assignment Suggestions** (optional)

Verify your suggested awarding component(s) (e.g., NIH Institute/Center) participate(s) in the Funding Opportunity. Use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below. All requests will be considered; however, assignment suggestions cannot always be honored.

Suggestions must be listed in the "Components of Participating Organizations" of the NOFO, or R&R Cover Form Box 4B must list an appropriate Notice of Special Interest.

Information about Awarding Component https://grants.nih.gov/grants/phs_assignr	can be found here: nent_information.htm#AwardingComponents
Suggested Awarding Components:	Suggestions are considered with other assignment
the study section "Anti-Infective Resistan	factors. Not all suggestions can be honored.  box below. Remove all hyphens, parentheses, and spaces. For example, enter "AIRT" to suggest ce and Targets", or B10 to suggest "Small Business: Biobehavioral Processes – BP (10)". All signment suggestions cannot always be honored.
Information about Study Sections can be	found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection
Suggested Study Sections:	Suggestions are considered with other assignment factors. Not all suggestions can be honored.
Rationale for assignment suggestions Explain why you think the suggestions are	(optional) e appropriate. If you contacted NIH staff, list their name(s). Entry is limited to 1000 characters.
Identify scientific areas of expertise ne Do not provide names of individuals. Eac	eded to review your application (optional) n entry is limited to 40 characters.
Limit your answers to evr	ertise. DO NOT enter the names of individuals you'd like to review your application.
List individuals who should not review Entry is limited to 1000 characters	
Provide specific reason v	ation (e.g., name organization affiliation) to correctly identify each individual.  why an individual should not review your application. Information will be individual does not guarantee they will not be on review panel.