Preview of FORMS-E Grant Application Form Changes

FORMS-E application forms required for NIH & AHRQ due dates on or after January 25, 2018

New PHS Human Subjects and Clinical Trials Information Form

PHS Human Subjects and Clinical Trials Information Form

Disclaimer

This resource is:

- A representation of the data items collected in the new PHS Human Subjects and Clinical Trials Information form
- Continuously evolving as we work through implementation details

This resource is NOT:

- A representation of the final look and feel of the form based on a pre-implementation form mock-up

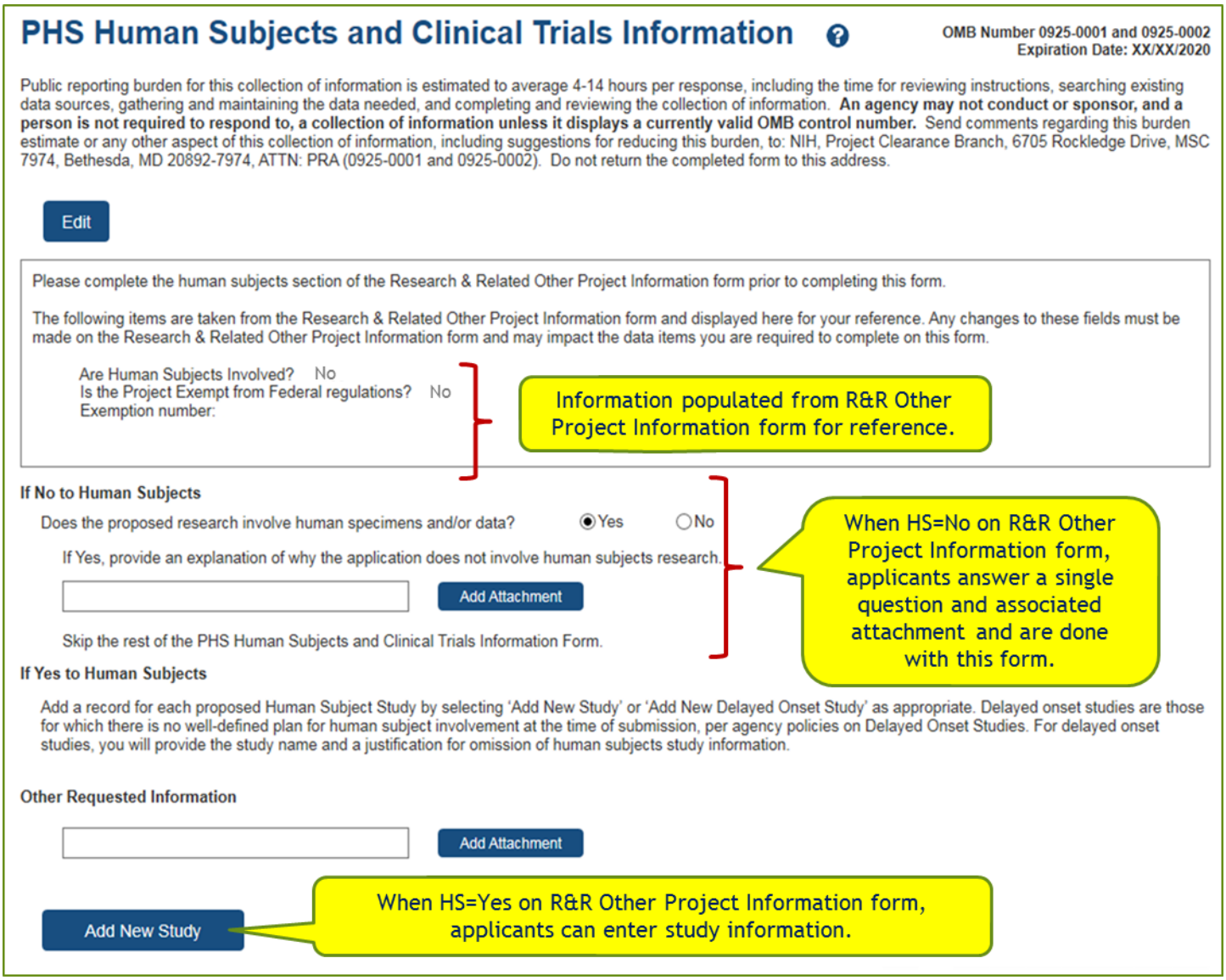
Goals

- Consolidate human subjects information currently scattered across multiple PHS forms within an application package
- Expand clinical trial data collection
    - Provide information needed for peer review
    - Position us for future data exchange with ClinicalTrials.gov

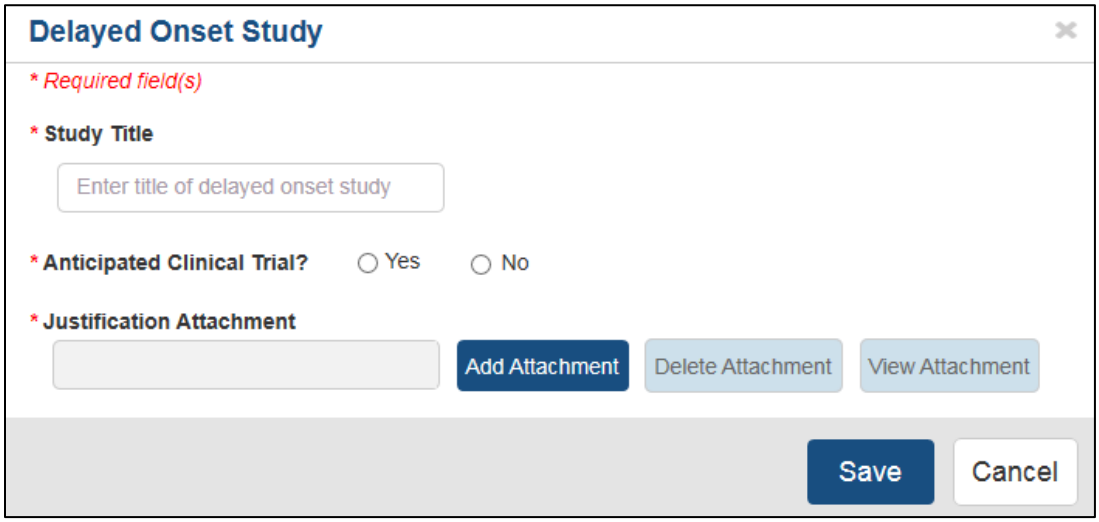
Getting Acclimated to New Form

- New form included in all applications (whether or not human subjects or clinical trials are involved)
- Collects study level information
- NIH will continue to collect some application level Human Subjects information on the Research & Related Other Project Information form
    - Used federal-wide, not within NIH control to remove Human Subjects questions from this form to our new PHS Human Subjects and Clinical Trials Information form
- When HS= Yes on Research & Related Other Project Information form applications must include one of the following on the new PHS Human Subjects and Clinical Trials Information Form
    - 1 or more full study records, OR
    - 1 or more delayed onset study records, OR
    - A combination of full and delayed onset study records
- Required form fields vary based on a number of factors, including:
    - Whether study is delayed onset
    - Announcement-specific instructions
    - Human subject exemptions
    - Whether study involves a clinical trial

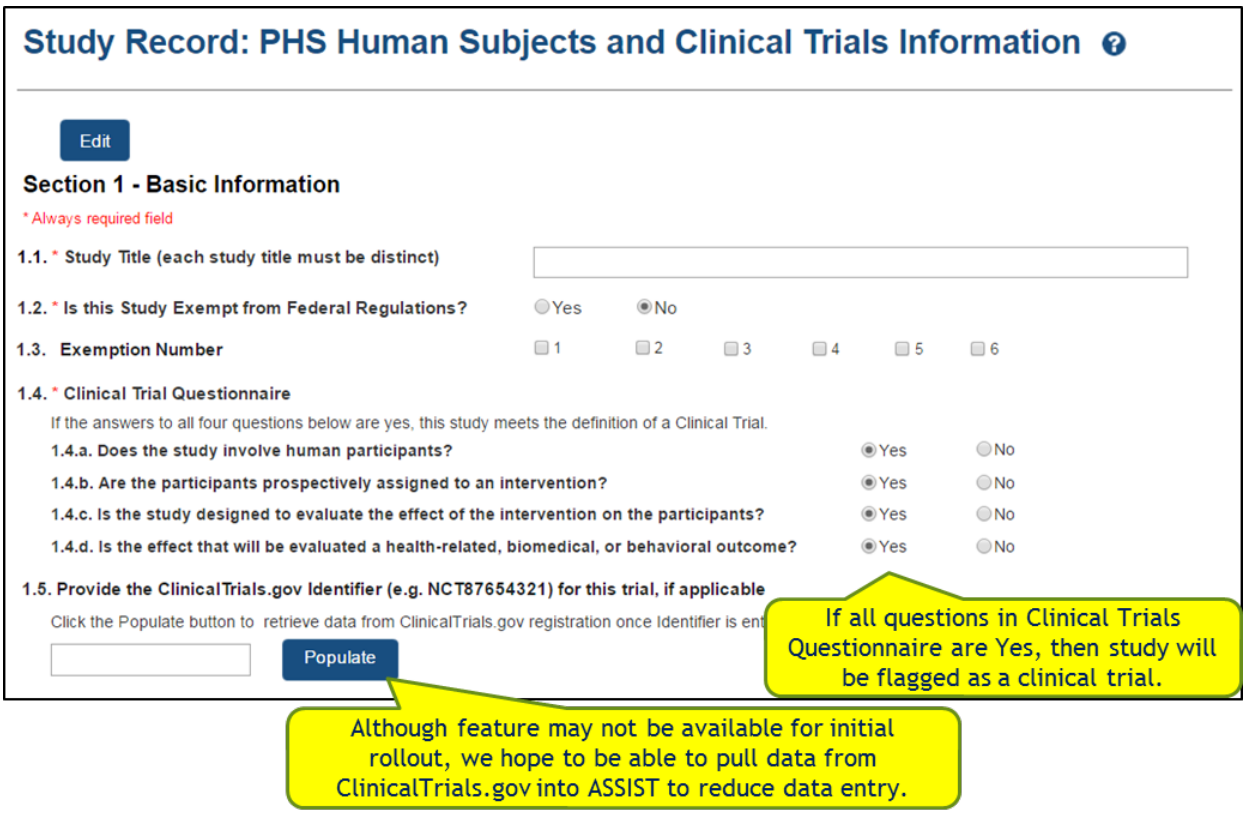
PHS Human Subjects and Clinical Trials Information Landing Page

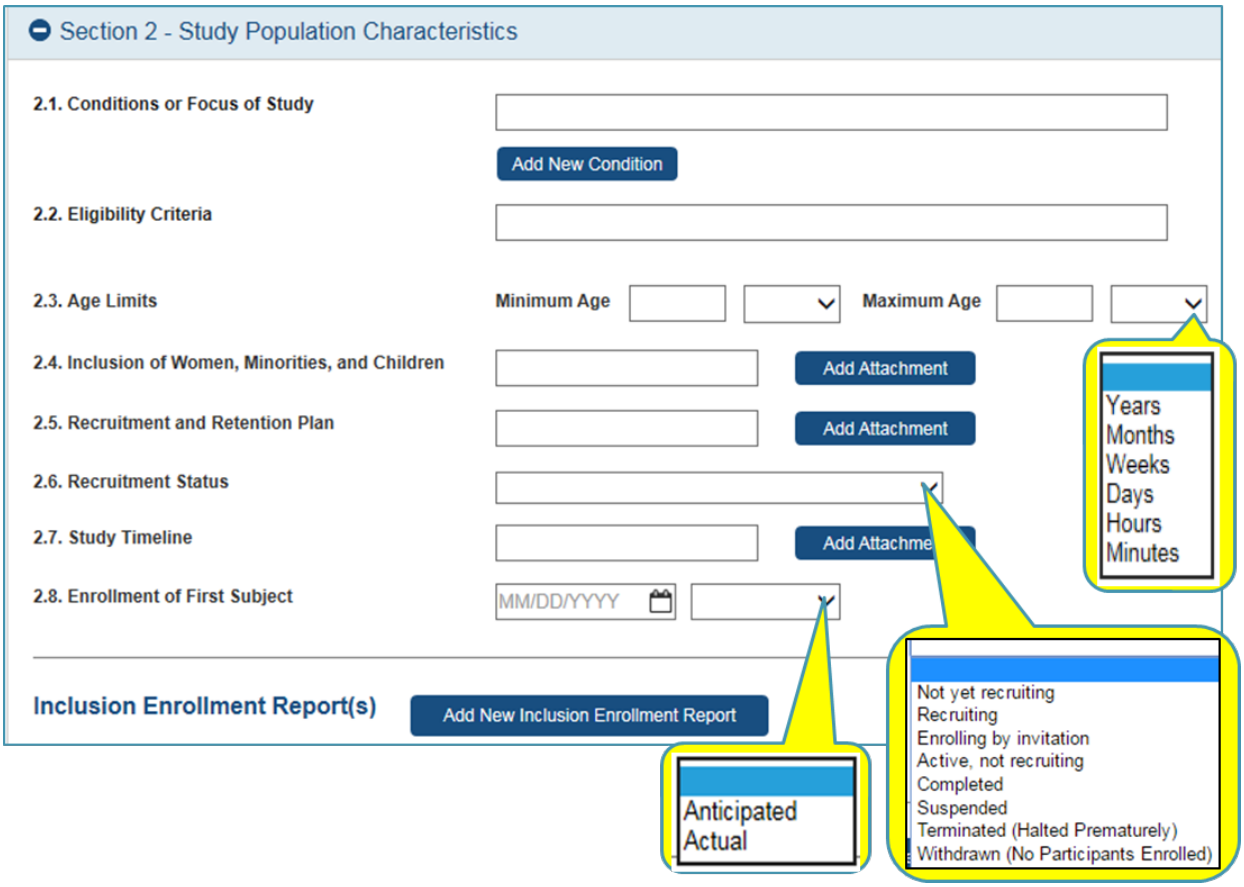


Data Collection for Delayed Onset Study



Full study records are comprised of 5 sections.





Inclusion Enrollment Report

Human Subjects Study <1>

Edit

1. * Using an Existing Dataset or Resource ○ Yes ◉ No
2. * Enrollment Location Type ◉ Domestic ○ Foreign
3. Enrollment Country(ies) UNITED STATES OF AMERICA
4. Enrollment Location(s)
5. Comments — Enter up to 500 characters

Characters Remaining: 500

Planned — Used when Existing Data Source or Resource = No

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

Cumulative (Actual) — Used when Existing Data Source or Resource = Yes

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

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects — Add Attachment

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

◉ Yes ○ No ○ N/A

If yes, describe the single IRB plan — Add Attachment

3.3. Data and Safety Monitoring Plan — MonitoringPlan.pdf — Replace Attachment | Delete Attachment | View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study? ◉ Yes ○ No

3.5. Overall structure of the study team — Add Attachment

Section 4 - Protocol Synopsis

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

- Treatment
- Prevention
- Diagnostics
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other

4.2.c. Interventions

Intervention Type	
Name	
Description	

- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Combination Product
- Diagnostic Test
- Other

Add New Intervention

4.2.d. Study Phase

- Early Phase 1 (or Phase 0)
- Phase 1
- Phase 1/2
- Phase 2
- Phase 2/3
- Phase 3
- Phase 4
- Other

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

4.2.e. Intervention Model

- Single Group
- Parallel
- Cross-Over
- Factorial
- Sequential
- Other

4.2.f. Masking ◉ Yes ○ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.2.g. Allocation

- N/A
- Randomized
- Non-randomized

4.3. Outcomes or Measures

Name	
Type	
Time Frame	
Brief Description	

Primary
Secondary
Other

Add New Outcome

4.4. Statistical Design and Power Add Attachment

4.5. Subject Participation Duration

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

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

Add Attachment

4.7. Dissemination Plan Add Attachment

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments Add Attachment

Attachment File Name	Delete On Save	Update Attachment	View Attachment
Attachment 1.pdf	☐	Update	View
Attachment 2.pdf	☐	Update	View

FORMS-E Changes in Agency-specific (PHS) Forms

PHS forms not included in this resource have not been changed except to update the form expiration date.

PHS 398 Career Development Award Supplemental Form

Requested form changes.

OMB Number: 0925-0001
Expiration Date: 10/31/2018

New date - 03/31/2020

Introduction

1. Introduction to Application (~~RESUBMISSION~~)		Add Attachment	Delete Attachment	View Attachment

Replace parenthetical text with "(for Resubmission and Revision applications)".

Candidate Section

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

Research Plan Section

3. Specific Aims		Add Attachment	Delete Attachment	View Attachment
4. * Research Strategy		Add Attachment	Delete Attachment	View Attachment
5. Progress Report Publication List (~~for RENEWAL applications only~~)		Add Attachment	Delete Attachment	View Attachment
6. Training in the Responsible Conduct of Research		Add Attachment	Delete Attachment	View Attachment

Replace parenthetical text with "(for Renewal applications)".

Other Candidate Information Section

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

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s)		Add Attachment	Delete Attachment	View Attachment
9. Letters of Support from Collaborators, Contributors, and Consultants		Add Attachment	Delete Attachment	View Attachment

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment		Add Attachment	Delete Attachment	View Attachment
11. Institutional Commitment to Candidate's Research Career Development		Add Attachment	Delete Attachment	View Attachment

~~Human Subject Sections~~

Remove this section (attachments 12-15) and renumber remaining form fields.

~~12. Protection of Human Subjects~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
~~13. Data Safety Monitoring Plan~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
~~14. Inclusion of Women and Minorities~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
~~15. Inclusion of Children~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~

PHS 398 Career Development Award Supplemental Form

Other Research Plan Sections

12.	16. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
13.	17. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
14.	18. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
15.	19. Resource Sharing		Add Attachment	Delete Attachment	View Attachment
16.	20. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

Appendix

17. 21. Appendix — Add Attachments | Delete Attachments | View Attachments

* Citizenship

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

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

- ☐ With a Permanent U.S. Resident Visa
- ☐ With a Temporary U.S. Visa
- ☐ Not Residing in the U.S.

~~If with a temporary U.S. visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, also check here~~: ☐

Replace sentence with "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:"

Requested form changes.

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 10/31/2018

New date - 03/31/2020

1. ~~Human Subjects Section~~

Remove this section (attachments 5-8) and renumber remaining form fields.

~~Clinical Trial?~~ ☐ ~~Yes~~ ☐ ~~No~~

~~*Agency-Defined Phase III Clinical Trial?~~ ☐ ~~Yes~~ ☐ ~~No~~

1. → **2. Vertebrate Animals Section**

Are vertebrate animals euthanized? ☐ Yes ☐ No

If "**Yes**" to euthanasia

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

If "**No**" to AVMA guidelines, describe method and provide scientific justification

2. → **3. *Program Income Section**

*Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☐ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

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

3. → **4. Human Embryonic Stem Cells Section**

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

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

Remove "please".

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

Cell Line(s) (Example: 0004):

PHS 398 Cover Page Supplement

4. **5. Inventions and Patents Section (RENEWAL)** ← Change parenthetical text to "for Renewal applications".

*Inventions and Patents: Yes ☐ No ☐

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

*Previously Reported: Yes ☐ No ☐

Remove spaces before and after "/" to read "Investigator/Change".

5. **6. Change of Investigator / Change of Institution Section**

Remove spaces before and after "/" to read "Director/Principal".

☐ Change of Project Director / Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

Requested form changes.

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

New date - 03/31/2020

Introduction

1. Introduction to Application (~~Resubmission and Revision~~)		Add Attachment	Delete Attachment	View Attachment

Replace parenthetical text with "(for Resubmission and Revision applications)".

Research Plan Section

2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment

~~Human Subjects Section~~

Remove this section (attachments 5-8) and renumber remaining form fields.

~~5. Protection of Human Subjects~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
~~6. Data Safety Monitoring Plan~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
~~7. Inclusion of Women and Minorities~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
~~8. Inclusion of Children~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~

Other Research Plan Section

5.	9. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
6.	10. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
7.	11. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
8.	12. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
9.	13. Letters of Support		Add Attachment	Delete Attachment	View Attachment
10.	14. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
11.	15. Authentication of Key Biological and/or Chemical Resources		Add Attachment	Delete Attachment	View Attachment

Appendix

12.	16. Appendix	Add Attachments	Delete Attachments	View Attachments

Requested form changes.

PHS 398 Research Training Program Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

New date - TBD.

Introduction

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

Replace parenthetical text with "(for Resubmission and Revision applications)".

Training Program Section

2. * Program Plan		Add Attachment	Delete Attachment	View Attachment
3. Plan for Instruction in the Responsible Conduct of Research		Add Attachment	Delete Attachment	View Attachment
4. Plan for Instruction in Methods for Enhancing Reproducibility		Add Attachment	Delete Attachment	View Attachment
5. Multiple PD/PI Leadership Plan (if applicable)		Add Attachment	Delete Attachment	View Attachment
6. Progress Report ~~(for RENEWAL applications only)~~		Add Attachment	Delete Attachment	View Attachment

Replace parenthetical text with "(for Renewal applications)".

Faculty, Trainees and Training Record Section

7. Participating Faculty Biosketches		Add Attachment	Delete Attachment	View Attachment
8. Letters of Support		Add Attachment	Delete Attachment	View Attachment
9. Data Tables		Add Attachment	Delete Attachment	View Attachment

Other Training Program Section

10. ~~Human Subjects~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
11. ~~Data Safety Monitoring Plan~~		~~Add Attachment~~	~~Delete Attachment~~	~~View Attachment~~
10. 12. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
11. 13. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
12. 14. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment

Remove these attachments (10-11) and renumber remaining form fields.

Appendix

13. 15. Appendix	Add Attachments	Delete Attachments	View Attachments

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 10/31/2018

New date - 03/31/2020.

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

~~If you have a preference for an Awarding Component (e.g., NIH Institute/Center) y~~ ~~nter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign~~ ~~quests will be considered; however, locus of review is predetermined for some applications and~~

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

Awarding Components: ~~*ng Components can be found here:*~~ https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

	First Choice ~~1~~	Second Choice ~~2~~	Third Choice ~~3~~
Assign to Awarding Component:			
Do Not Assign to Awarding Component:			

Study Section Assignment Request *(optional)*

~~If you have a preference for a study section ass~~ ~~ter the short abbreviation for that study section in "Assign to/Do not Assign to Study Section" sect~~ ~~ever, locus of review is predetermined for some applications and assignment requests cannot a~~

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

~~For example, you would enter "CAMP" if you wi~~ ~~RG1 HDM-R" if you wish to request assignment to the Healthcare Delivery and Methodologies S~~ ~~aces, hyphens) when you type in the request.~~

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

	First Choice ~~1~~	Second Choice ~~2~~	Third Choice ~~3~~
Assign to Study Section: *Only 20 characters allowed*			
Do Not Assign to Study Section: *Only 20 characters allowed*			

PHS Assignment Request Form

Lower case "i" in "individuals."

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

Make sure applicants can provide 1000 characters of text, even if it extends past 8 lines.

Lower case "s" in "scientific."

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

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

Requested form changes.

PHS Fellowship Supplemental Form

OMB Number: 0925-0001
Expiration Date: 10/31/2018

New date - 03/31/2020.

Introduction

1. Introduction (~~RESUBMISSION~~)

Change to "Introduction to Application".

Change parenthetical text to "(for Resubmission applications)".

Add Attachment | Delete Attachment | View Attachment

Fellowship Applicant Section

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

Research Training Plan Section

3. * Specific Aims — Add Attachment | Delete Attachment | View Attachment
4. * Research Strategy — Add Attachment | Delete Attachment | View Attachment
5. * Respective Contributions — Add Attachment | Delete Attachment | View Attachment
6. * Selection of Sponsor and Institution — Add Attachment | Delete Attachment | View Attachment
7. Progress Report Publication List (~~RENEWAL~~) — Add Attachment | Delete Attachment | View Attachment

Change parenthetical text to "(for Renewal applications)".

8. * Training in the Responsible Conduct of Research — Add Attachment | Delete Attachment | View Attachment

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

9. Sponsor and Co-Sponsor Statements — Add Attachment | Delete Attachment | View Attachment
10. Letters of Support from Collaborators, Contributors, and Consultants — Add Attachment | Delete Attachment | View Attachment

Institutional Environment and Commitment to Training Section

11. Description of Institutional Environment and Commitment to Training — Add Attachment | Delete Attachment | View Attachment

Other Research Training Plan Section

Keep section heading to encompass Vertebrate Animals and Other Research Training Plan Information sub-sections.

~~**Human Subjects**~~

Remove this sub-section (attachments 12-18) and renumber remaining form fields.

~~Please note. The following item is taken from the Research & Related Other Project Information form. The response provided on that page, regarding the involvement of human subjects, is repeated here for your reference as you provide related responses for this Fellowship application. If you wish to change the answer to the item shown below, please do so on the Research & Related Other Project Information form; you will not be able to edit the response here.~~

~~Are Human Subjects Involved?~~ ☐ ~~Yes~~ ☐ ~~No~~

12. ~~Human Subjects Involvement Indefinite?~~ ☐ ~~Yes~~ ☐ ~~No~~
13. ~~Clinical Trial?~~ ☐ ~~Yes~~ ☐ ~~No~~
14. ~~Agency-Defined Phase III Clinical Trial?~~ ☐ ~~Yes~~ ☐ ~~No~~
15. ~~Protection of Human Subjects~~ — ~~Add Attachment~~ | ~~Delete Attachment~~ | ~~View Attachment~~
16. ~~Data Safety Monitoring Plan~~ — ~~Add Attachment~~ | ~~Delete Attachment~~ | ~~View Attachment~~
17. ~~Inclusion of Women and Minorities~~ — ~~Add Attachment~~ | ~~Delete Attachment~~ | ~~View Attachment~~
18. ~~Inclusion of Children~~ — ~~Add Attachment~~ | ~~Delete Attachment~~ | ~~View Attachment~~

Requested form changes.

PHS Fellowship Supplemental Form

Vertebrate Animals

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

Are Vertebrate Animals Used? ☐ Yes ☐ No

19. ~~Vertebrate Animals Use Indefinite?~~ ☐ ~~Yes~~ ☐ ~~No~~ ← Remove this attachment and renumber remaining form fields.

12. → 20. Are vertebrate animals euthanized? ☐ Yes ☐ No

If "**Yes**" to euthanasia

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

If "**No**" to AVMA guidelines, describe method and provide scientific justification

13. → 21. Vertebrate Animals [ ] Add Attachment | Delete Attachment | View Attachment

Other Research Training Plan Information

14. → 22. Select Agent Research [ ] Add Attachment | Delete Attachment | View Attachment

15. → 23. Resource Sharing Plan [ ] Add Attachment | Delete Attachment | View Attachment

16. → 24. Authentication of Key Biological and/or Chemical Resources [ ] Add Attachment | Delete Attachment | View Attachment

Additional Information Section

17. → **25. Human Embryonic Stem Cells** ← Remove underline and bold formatting.

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

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

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

Cell Line(s):

[ ]

18. → 26. Alternate Phone Number: [ ]

19. → 27. Degree Sought During Proposed Award:

Remove "please".

Degree: [ ] If "other", ~~please~~ indicate degree type: [ ] Expected Completion Date (~~month/year~~): [ ] Reset Entry

Change parenthetical text "MM/YYYY".

20. → 28. * Field of Training for Current Proposal: [ ]

PHS Fellowship Supplemental Form

Lower case "o" in "or".

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

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

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

22. 30. * Applications for Concurrent Support ☐ Yes ☐ No

If yes, ~~please~~ describe in an attached file: Add Attachment | Delete Attachment | View Attachment

Remove "please".

23. 31. * Citizenship:

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

Non-U.S.Citizen

☐ With a Permanent U.S. Resident Visa

☐ With a Temporary U.S. Visa

~~If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, please also check here.~~ ☐

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

24. 32. ☐ Change of Sponsoring Institution

Name of Former Institution:

Budget Section

All Fellowship Applicants:

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

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

Senior Fellowship Applicants Only:

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

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

	Amount	Number of Months
a. Federal Stipend Requested:		
b. Supplementation from other sources:		

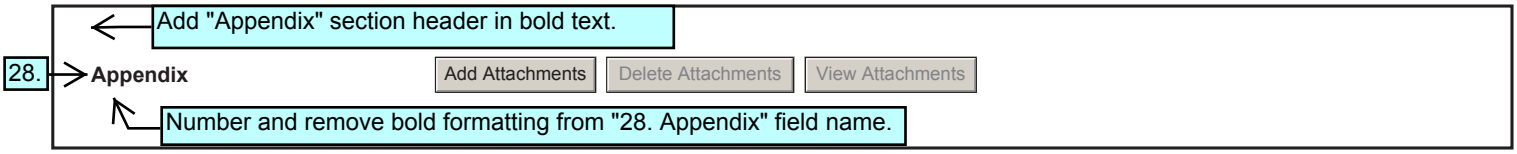
Capital "0" and "S" in "Other Sources".

Type (~~sabbatical leave, salary, etc.~~)

Change parenthetical text to - "(e.g., sabbatical leave, salary)".

Source

PHS Fellowship Supplemental Form



FORMS-E Changes in Federal-wide (Research & Related) Forms

Federal-wide Research & Related forms not included in this resource have not been changed except to update the form expiration date.

Implemented form changes.

RESEARCH & RELATED BUDGET - Budget Period 1

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

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

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

A. Senior/Key Person

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

Project Role: PD/PI

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

B. Other Personnel

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

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)

C. Equipment Description

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

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees — **Total Participant/Trainee Support Costs**	

F. Other Direct Costs

		Funds Requested ($)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
	Total Other Direct Costs	

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)

Total Indirect Costs

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

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	

J. Fee

Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	

New Total Costs and Fees Calculation

L. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		New Total Costs and Fees Calculation

Implemented form changes.

SBIR/STTR Information

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

*** Agency to which you are applying (select only one)** ← New field.

☐ DOE ☐ HHS ☐ USDA ☐ Other: _____

*** SBC Control ID:** _____ *(This 9 digit code is obtained from the Small Business Administration)* ← New field.

*** Program Type (select only one)**

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

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

☐ Phase I ☐ Phase II ☐ Fast-Track ☐ Direct Phase II ☐ Phase IIA ☐ Phase IIB
☐ Commercialization Readiness Program *(See agency-specific instructions to determine application type participation.)*

Added "Direct Phase II", "Phase IIA", "Phase IIB" and "Commercialization Readiness Program" as Application Type options

Phase I Letter of Intent Number: _____ ← New field.

*** Agency Topic/Subtopic:** _____ ← New field.

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

☐ Yes ☐ No	* 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award. _____
☐ Yes ☐ No	* 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? ← New question.
☐ Yes ☐ No	* 1d. Is your small business a Faculty or Student-Owned entity? ← New question.
☐ Yes ☐ No	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? * If yes, insert the names of the Federal laboratories/agencies:
☐ Yes ☐ No	* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov
☐ Yes ☐ No	* 4. Will all research and development on the project be performed in its entirety in the United States? If no, provide an explanation in an attached file. * Explanation: _____ Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? * If yes, insert the names of the other Federal agencies:
☐ Yes ☐ No	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? ← Text updated.
	* 7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase I/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * Attach File: _____ Add Attachment Delete Attachment View Attachment

SBIR/STTR Information

SBIR-Specific Questions:

Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

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

STTR-Specific Questions:

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

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