



Research IT

Instructions for InfoEd S2S NIH

Human Subjects and Clinical Trials Information Form

For NIH Applications with Due Dates On Jan 25, 2018 and After

The instructions for completing this form are on the NIH website. Please refer to the following resources.

1. Video (approx. 9 minutes)- [A Walk-through of the PHS Human Subjects and Clinical Trials Information Form](#)
2. Instructions - SF 424 Application Guide > G.500
[PHS Human Subjects and Clinical Trials Information Form](#)


The instructions on the following pages supplement the NIH instructions to explain variations of the Human Subject and Clinical Trials Information Form in InfoEd and to highlight technical or other important requirements (e.g., term definition, character limit, unique title requirement, etc.). The links within these InfoEd instructions bring the user to the particular portion of the NIH instructions.

Other Resources

3. Podcast (approx. 12 minutes)- [Understanding the Definition of a Clinical Trial and What That Means for You](#)
4. Video (approx. 15 minutes) - [Overview of New NIH Policies on Human Subjects Research and Clinical Trials](#)

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Need Help? [Open Ticket with Research IT](#) or click on the  **Support** icon on the left side navigation bar.

Setup Questions

SF424 (R&R)

Other Project Info

Performance Sites

Personnel

Budget

PHS 398 Cover

Page Supplement

PHS 398 Research Plan

New / Competitive

Renewals / Re...

Internal Document

Human Subjects/CT

Approvals

Finalize

1. Click on Human Subjects/CT.
2. If No to Human Subjects, you must answer the questions as indicated.
3. If Yes to Human Subjects, add a New Study or a New Delayed Onset Study.
4. If you are adding a new study, enter a unique title no longer than 600 characters and then click on the Add New Study button for each [human subject study record](#). This form accommodates up to 150 separate New Study Records. Instructions continue in Step 8.
5. If you are adding a [new delayed onset study](#), enter a unique title no longer than 600 characters. Instructions continue in Step 20.
6. Follow the [other requested information instructions](#) and any instructions in your Funding Opportunity Announcement (FOA) to determine whether you are permitted to include Other Requested Information. **If it's not permitted, do not attach a file.**

Human Subjects/CT

Completed

7. The user can check for technical errors prior to submission. Instructions continue in Step 22.

OMB Number: 0925-000
Expiration Date: 03/31/2020

Validate XML & NIH Pre-Submission

* All mandatory data elements (fields/uploads) on all screens must be addressed in order to submit for NIH pre-submission validation.

Are Human Subjects Involved?

Yes

No

(set on Setup Questions tab)

Is the Project Exempt from Federal regulations?

Yes

No

(set on Other Project Information tab)

Exemption number:

1

2

3

4

5

6

7

8

(set on Other Project Information tab)

If No to Human Subjects

Does the proposed research involve human specimens and/or data? Yes No

If Yes, provide an explanation of why the application does not involve human subjects research. Add Attachment

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

If Yes to Human Subjects

Add an appropriate record for each proposed Human Subject Study

"Add New Study"

Or

"Add New Delayed Onset Study"

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.

Attach file to Other Requested Information per funding announcement and/or agency-specific instructions.

Other Requested Information

Original

PDF

Add Attachment

Study Record(s) [Hide]

Study Title

No records to display.

Enter Study Title (each study title must be unique)

Add New Study

Delayed Onset Study(ies)

Study Title

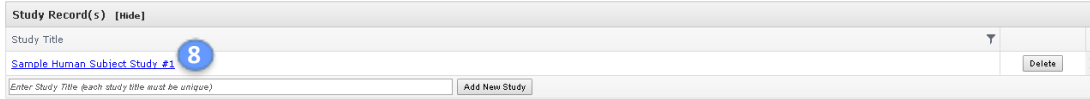
No records to display.

Enter Study Title (each study title must be unique)

Add New Delayed Onset Study

Study Title
-
Max. of 600 characters.

Delayed Onset – Human subjects research is anticipated within period of award but definite plans for this involvement cannot be described in the application.



8. After you add the New Study Record (see step 4), a link appears to the newly created record. Click on the link and complete the new Study Record sub-form. A screenshot of the Study Record sub-form is below.
9. **Section 1 - All applications must have sections 1.1 – 1.4 completed.** See 1.5 in the [NIH Instructions](#) for information about the ClinicalTrials.gov identifier.
10. **Section 2 – This entire section is required for most human subject studies.** See section 2 of the [NIH instructions](#) for complete information.
11. An Inclusion Enrollment Report (IER) sub-form is required for all human subject studies unless it falls under Exemption 4 and no other exemptions. Click on the Add Inclusion Enrollment Report button to add the sub-form. Refer to [NIH’s Inclusion Enrollment Report instructions](#). The following page shows a screenshot of the IER.

New Study Record Form

This is an image of the top portion, sections 1 – 2, of the New Study Record sub-form.

Study Record: PHS Human Subjects and Clinical Trials Information Completed

*** Always required field**

Section 1 - Basic Information

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

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

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

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

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

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

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

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

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT07654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study
2.1 Minimum of 1 Entry / Maximum of 20. Each entry limited to 255 characters.

2.2. Eligibility Criteria
2.2 Text entry limited to 15,000 characters.

2.3. Age Limits Minimum Age Maximum Age

2.4. Inclusion of Women, Minorities, and Children

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Inclusion Enrollment Report (IER)

The Inclusion Enrollment Report form is a sub-form within the Human Subjects and Clinical Trials Information > Add New Study Record form. See Step 11 on preceding page. **Answer the questions as per the NIH instructions.**

12. Questions 1-2 are required. 3-4 is optional. See notes in the screenshot below.
13. Click on Next Report to add more Inclusion Enrollment Reports.
14. Check Completed once the form is complete. To edit form, remove the checkmark.

12
Max of 20 IERs per study record. This can be a combination of planned and cumulative reports.
14

Inclusion Enrollment Report Completed

1. * Using an Existing Dataset or Resource Yes No

2. * Enrollment Location Type Domestic Foreign

3. Enrollment Country(ies) Delete

Add New Country

4. Enrollment Location(s)

5. Comments

Comments limited to 500 characters.

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

Planned Enrollment Table
You must enter planned enrollment counts if your proposed study will not use an existing dataset or resource.

Cumulative (Actual)

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

Cumulative Table
You must enter cumulative enrollment counts if your proposed study will use an existing dataset or resource.

< Previous Report
Report 1 of 1
Next Report >

<< First Report
Delete Report
Last Report >>

13

New Study Record Form (continued)

This is section 3 – 4.2, the middle portion, of the New Study Record form.

Section 4 continues on the next page.

15. Section 3 – This entire section is required for all studies involving human subjects, unless otherwise noted in the [NIH instructions](#).
16. Section 4 – This entire section is required for all studies that include the answer Yes in 1.4 the [Clinical Trial Questionnaire](#). See Step 9 of these instructions. Refer to the [NIH instructions](#) for complete information. Do not complete this section if you answered No to any question in 1.4. If you do, this will result in errors and will prevent your application from being accepted.
17. Click to Add New Intervention. Review section 4 instructions (link above) for applicability.

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 Add 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 4.1 limited to 5,000 characters.

4.2. Study Design

4.2.a. Narrative Study Description 4.2.a limited to 32,000 characters.

4.2.b. Primary Purpose 4.2.b > Other limited to 255 characters.

4.2.c. Interventions

Intervention Type	Name	Description	Actions
			<input type="checkbox"/> Add <input type="checkbox"/> Edit <input type="checkbox"/> Delete

Name limited to 200 characters.
Description limited to 1,000 characters.

Users can add up to 20 interventions.

4.2.d. Study Phase Is this an NIH-defined Phase III clinical trial? Yes No

4.2.e. Intervention Model 4.2.e > Other limited to 255 characters.

4.2.f. Masking Yes No
 Participant Care Provider Investigator Outcomes Assessor

4.2.g. Allocation

New Study Record Form (continued)

This is section 4.3 - 5, the bottom portion, of the New Study Record form. See Step 16 overall re: section 4 requirements.

18. Click to Add New Outcome (i.e., Primary, Secondary, Other).
19. **Section 5 – This section is required for all studies if two criteria are met.**
 - 1) You’ve included the answer Yes to all questions in 1.4 the Clinical Trial Questionnaire, and
 - 2) The funding opportunity announcement specifies that an attachment(s) is required or permitted.

Do not complete this section if you answered No to any question in 1.4. If you do, this will result in errors and will prevent your application from being accepted.

The screenshot shows the bottom portion of the New Study Record form. It includes sections 4.3 through 4.7, and Section 5. Red callout boxes provide additional information:

- 4.3. Outcome Measures:** A table with columns for Name, Type, Time Frame, and Description. A red box above the table states "4.3 limited to 50 outcome measures." A red box over the Description field states "Description limited to 999 characters." Below the table is an "Add New Outcome" button with a circled "18".
- 4.4. Statistical Design and Power:** Includes an "Add Attachment" button.
- 4.5. Subject Participation Duration:** A text input field with a red box stating "4.5 limited to 255 characters."
- 4.6. Will the study use an FDA-regulated intervention?** Radio buttons for Yes and No.
- 4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status** (Text input field)
- 4.7. Dissemination Plan:** Includes an "Add Attachment" button.
- Section 5 - Other Clinical Trial-related Attachments:** A header for the next section.
- 5.1. Other Clinical Trial-related Attachments:** Includes an "Add Attachment" button and a red box stating "Max of 10 attachments." with a circled "19".

New Delayed Onset Study

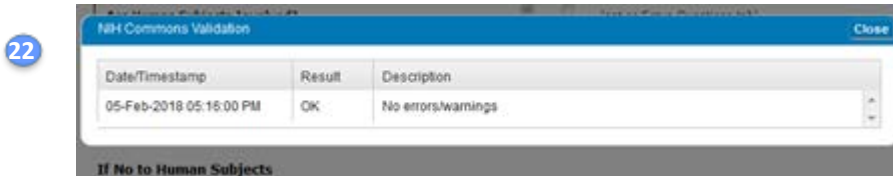
This is a continuation from Step 5. Refer to the [NIH instructions](#) for more information about delayed onset studies.

- 20. Check this box if you anticipate that this study will be a [clinical trial](#).
- 21. Upload the justification. If you are including more than one delayed onset study in any given delayed onset study entry, address all the included studies in a single justification attachment.

Delayed Onset Study(ies) [Hide]				
Study Title	Anticipated Clinical Trial?	Justification		
		Original	PDF	
Delayed Onset Study #1	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Delete"/>
<small>Enter Study Title (each study title must be unique)</small>		<input type="button" value="Add New Delayed Onset Study"/>		

Pre-Submission Validation Feature on the Human Subjects and Clinical Trials Information Form

22. This is a continuation from Step 7. The user can check for technical errors prior to GCO submission. In order to use this feature, the user must complete the mandatory date elements on all the InfoEd tabs. After that requirement is met, click the pre-validation button (Step 7) and a Validation pop up box appears. See sample below.



Final Step on Human Subjects and Clinical Trials Information Form

23. Place checkmark in Completed box once complete. To edit the form, remove the checkmark.

