



Icahn School
of Medicine at
Mount
Sinai

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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Last Updated: 1/19/2018

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

PHS398 Cover Page Supplement

PHS398 Research Plan

New / Competitive Renewals / Re ...

Internal Document

1 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. This instruction set will be updated once this option is available. The user can check for technical errors prior to submission.

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

7 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 numbers: 1 2 3 4 5 6 7 8 (set on Other Project Information tab)

If No to Human Subjects**2**

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**3**

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

6**Study Record(s) [Hide]**

Study Title

No records to display.

Enter Study Title (each study title must be unique)

4

Add New 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.

Study Title

Anticipated Clinical Trial?

Original

PDF

No records to display.

Enter Study Title (each study title must be unique)

5

Add New Delayed Onset Study

Study Record(s) [Hide]

Study Title

Sample Human Subject Study #1 8

Enter Study Title (each study title must be unique)

Add New Study | Delete

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 Clinical Trials.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.

Setup Questions
SF314 (RBR)
Other Project Info
Performance Sites
Personnel
Budget
PHS 308 Cover Page Supplement
PHS 308 Research Plan
New / Competitive Renewals / Re
Internal Documents
Human Subject/CT
...

Study Record: PHS Human Subjects and Clinical Trials Information Completed

9 * 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.

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

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

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

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

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

10 **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) **11**

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
14

Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource Yes No

2. * Enrollment Location Type Domestic Foreign

3. Enrollment Country(ies)

4. Enrollment Location(s)

5. Comments

Comments limited to 500 characters.

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

Completed

Planned
Planned Enrollment Table

Racial Categories	Ethnic Categories					
	Not Hispanic or Latino		Hispanic or Latino		Total	
Female	Male	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						

Cumulative (Actual)

Racial Categories	Ethnic Categories							
	Not Hispanic or Latino			Hispanic or Latino		Unknown/Not Reported Ethnicity	Total	
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								
Total								

Cumulative Table

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

13

4

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

5

3.1. Protection of Human Subjects

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

Yes No N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

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

Yes No

3.5. Overall Structure of the Study Team

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	<input type="button" value=""/>
Name	<input type="button" value=""/>
Description	<input type="button" value=""/>

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

6

17 **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.

4.3 limited to 50 outcome measures.

Name	<input type="text"/>
Type	<input type="text"/>
Time Frame	<input type="text"/>
Description	<input type="text"/>

Description limited to 999 characters.

4.3. Outcome Measures

Add New Outcome **18**

4.4. Statistical Design and Power

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

4.7. Dissemination Plan

4.5 limited to 255 characters.

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

4.7. Dissemination Plan

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Add Attachment **19**

Max of 10 attachments.

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				
Delayed Onset Study #1	<input checked="" type="checkbox"/> 20	<table border="1" style="width: 100px; text-align: center;"> <tr> <td>Original</td> <td>PDF</td> </tr> <tr> <td><input type="button" value="Upload"/></td> <td><input checked="" type="checkbox"/> 21</td> </tr> </table>	Original	PDF	<input type="button" value="Upload"/>	<input checked="" type="checkbox"/> 21
Original	PDF					
<input type="button" value="Upload"/>	<input checked="" type="checkbox"/> 21					
<input type="text" value="Enter Study Title (each study title must be unique)"/>		<input type="button" value="Delete"/>				
<input type="button" value="Add New Delayed Onset Study"/>						

Final Step on Human Subjects and Clinical Trials Information Form

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

Proposal
PD17-07988

[Done](#) [Save](#)

- [Setup Questions](#)
- [SF424 \(R&R\)](#)
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NIH Human Subject Study
Allison Gottlieb - Grants and Contracts Office (National Institutes Of Health/DHHS)

22 [Proposal](#)

Human Subjects/CT Completed

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?		<input checked="" type="radio"/> Yes	<input type="radio"/> No	(set on Setup Questions tab)
Is the Project Exempt from Federal regulations?		<input checked="" type="radio"/> Yes	<input type="radio"/> No	(set on Other Project Information tab)
Exemption number:		<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <small>(set on Other Project Information tab)</small>		

If No to Human Subjects
Does the proposed research involve human specimens and/or data? Yes No [Add Attachment](#)
If Yes, provide an explanation of why the application does not involve human subjects research.
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	<input type="button" value="Add Attachment"/>	Original <input type="checkbox"/>
		PDF <input type="checkbox"/>