

NIH Human Subjects and Clinical Trials Guide

(To be used after January 2018)

NIH has changed their data collection strategy, and some of the forms have been consolidated. Please watch the Youtube video and follow the instructions below.

PHS HOW TO VIDEO YOUTUBE


https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1

- The answers to the Research & Related Other Project Information form drive (auto input) the PHS Human Subjects and Clinical Trials form (R&R)

RESEARCH & RELATED Other Project Information	
1. *	Are Human Subjects Involved? <input checked="" type="radio"/> Yes <input type="radio"/> No
1.a	If YES to Human Subjects
	Is the Project Exempt from Federal regulations? <input type="radio"/> Yes <input checked="" type="radio"/> No
	If yes, check the appropriate exemption number:
	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
	If no, is the IRB review Pending? <input checked="" type="radio"/> Yes <input type="radio"/> No
	IRB Approval Date: <input type="text"/>
	Human Subject Assurance Number: <input type="text" value="00005994"/>

- A. If NO to Human Subjects: **Stop here.**
- B. If YES to Human Subjects: **You MUST provide at least (1) Study Record in the PHS HS/CT form AND at least (1) Inclusion Enrollment Report:**
(A Full Detail Study Record **OR** a Delayed Onset Study Record)

PHS Human Subjects and Clinical Trials Information

If Yes to Human Subjects		
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 the study name and a justification for omission of human subjects study information.		
Study Record(s)		
Attach human subject study records using unique Study Titles.		
<input type="button" value="Add New Study"/> <input type="button" value="Import Study"/>		
#	Study Title	Is a Clinical Trial
1	ABC TEST	<input type="checkbox"/> 

(A) Full Study Record (5 sections)

The first four questions (1.4 a-d) under Human subjects determines if your project meets the definition of a **Clinical Trial**. If the answer to **ALL** four questions is **YES**, then the proposal meets the definition of Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information: 1

Study Record: PHS Human Subjects and Clinical Trials Information

Section 0 - Composite PDF

	Final	Draft	
Composite PDF ?	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>

Section 1 - Basic Information

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

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?	<input type="radio"/> Yes	<input type="radio"/> No
1.4.b. Are the participants prospectively assigned to an intervention?	<input type="radio"/> Yes	<input type="radio"/> No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	<input type="radio"/> Yes	<input type="radio"/> No
1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?	<input type="radio"/> Yes	<input type="radio"/> No

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

Section 2 - Study Population Characteristics

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

2.2. Eligibility Criteria

2.3. Age Limits

Minimum Age Maximum Age

	Final	Draft	
2.4 Inclusion of Women, Minorities, and Children	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>
2.5 Recruitment and Retention Plan	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>

2.6. Recruitment Status

White	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
More than One Race	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Unknown or Not Reported	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Total	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Section 3 - Protection and Monitoring Plans

For **HUMAN SUBJECTS ONLY**: Respond to ALL questions and **STOP** after 3.2 (Multi-Site question) is answered.
 For **CLINICAL TRIALS ONLY**: Complete the rest of the application fields: 3.3-3.5, Section 4 and 5.

Section 3 - Protection and Monitoring Plans

	Final	Draft	
3.1 Protection of Human Subjects	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>

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

	Final	Draft	
If yes, describe the single IRB Plan	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>

3.3 Data and Safety Monitoring Plan	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>
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3.4. Will a Data and Safety Monitoring Board be appointed for this study?
 Yes No

STOP after 3.2 for **Human Subjects Only**. The rest is to be completed for **Clinical Trials**.

	Final	Draft	
3.5 Overall Structure of the Study Team	No final --	No draft --	<input type="button" value="Add"/> <input type="button" value="Delete"/>

Section 4 - Protocol Synopsis

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

X	Intervention Type	<input type="text" value="Please Select..."/>
	Name	<input type="text"/>
	Description	<input type="text"/>

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

4.2.e. Intervention Model **Please Select...** ▼

4.2.f. Masking
 Yes No

Participant Care Provider Investigator Outcomes Assessor

4.2.g. Allocation **Please Select...** ▼

4.3. Outcome Measures

X	Name	Type	Time Frame	Brief Description
		Please Select... ▼		

Add New Outcome

	Final	Draft	
4.4 Statistical Design and Power	No final --	No draft --	Add Delete

4.5. Subject Participation Duration

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

	Final	Draft	
4.6.a If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status	No final --	No draft --	Add Delete
4.7 Dissemination Plan	No final --	No draft --	Add Delete

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

	Final	Draft	
<input type="text" value="1"/>	No final --	No draft --	Add Delete

(B) Delayed Onset Study Record (not Delayed Start)

(NIH glossary) Delayed Study Record is defined as human subjects research that is anticipated within the period of award, but definite plans for this involvement cannot be described in the application.

Identify a Study title

- a) Check the Anticipated Clinical Trial
- b) Upload a justification as to why the CT is delayed, and the details are not available at the time of application. Include an assurance that all clinical policies will be followed, IRB and plans for the dissemination of CT information in the commentary.