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? (•) Yes ( ) No
1.a If YES to Human Subjects
Is the Project Exempt from Federal regulations? ( ) Yes (•) No
If yes, check the appropriate exemption number:
Exemption Number: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ] 8
If no, is the IRB review Pending? (•) Yes ( ) No
IRB Approval Date:
Human Subject Assurance Number: 00005994

A. **<u>If NO to Human Subjects:</u>** **Stop here.**
B. **<u>If YES to Human Subjects:</u>** **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)

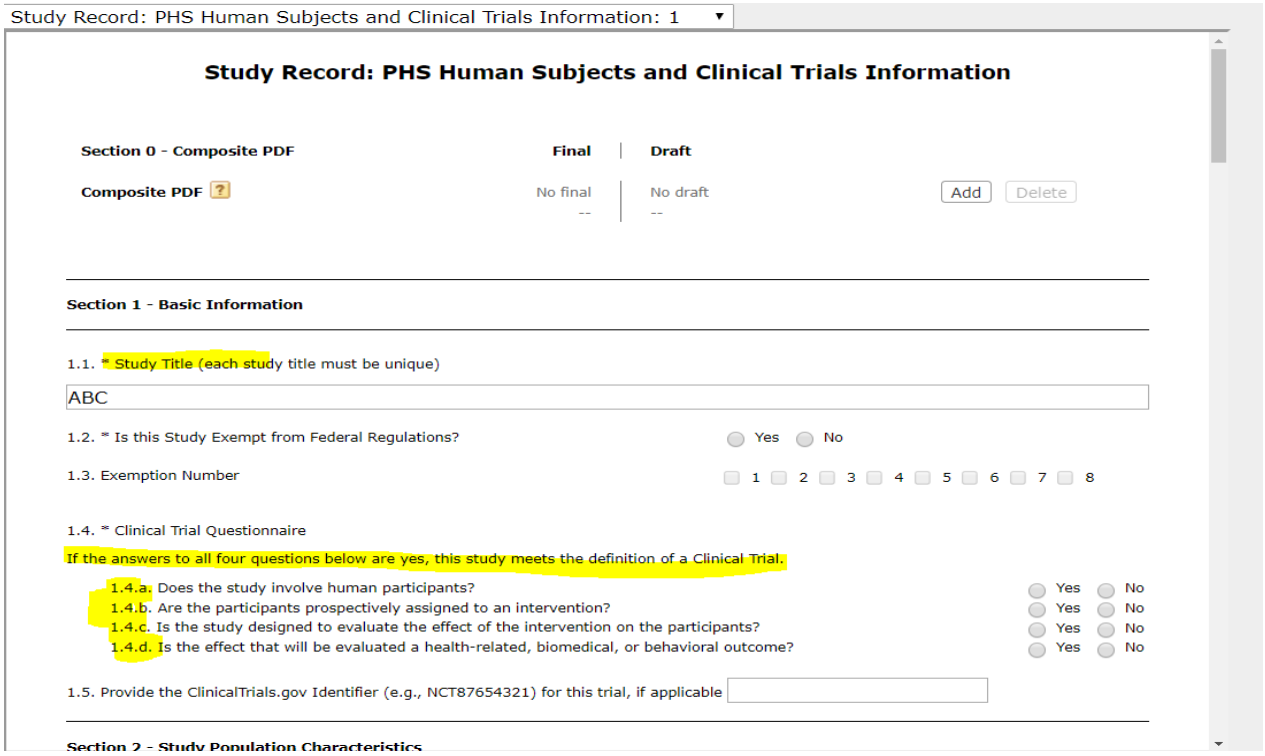
Attach human subject study records using unique Study Titles.

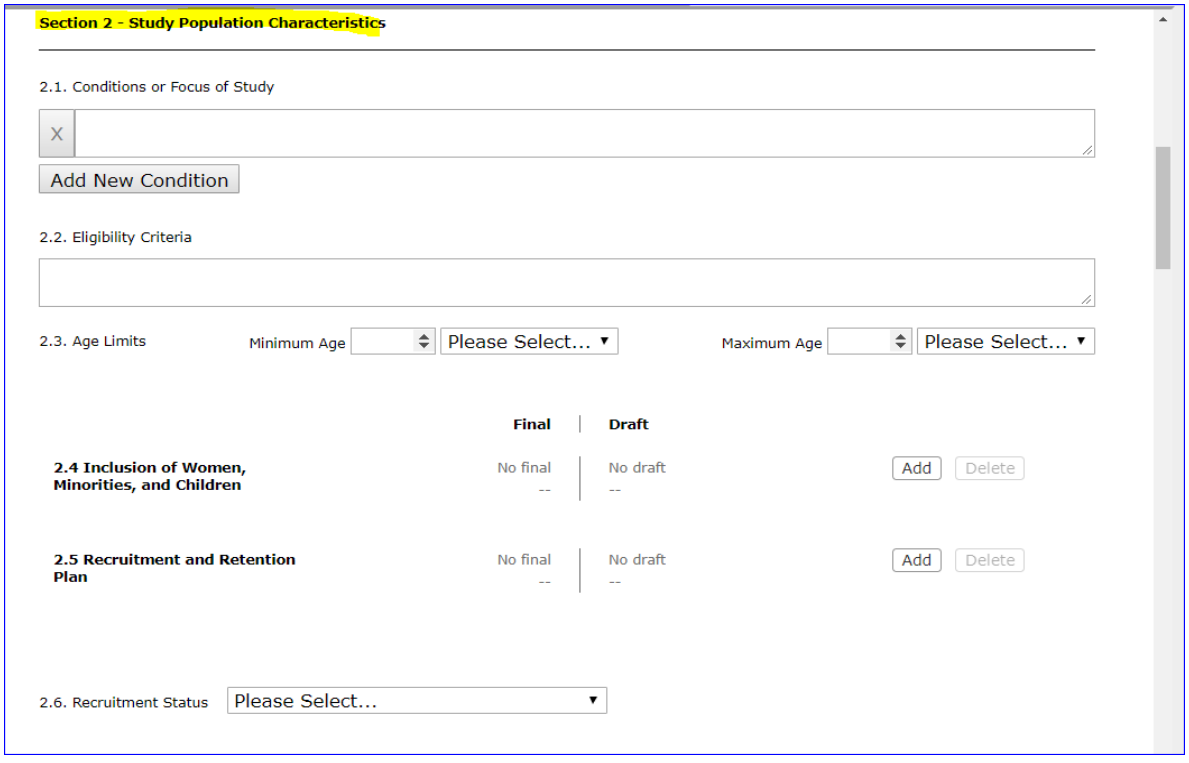
Add New Study | Import Study

#	Study Title	Is a Clinical Trial	
1	ABC TEST	☐	✖

(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





2.6. Recruitment Status Please Select...

	Final	Draft	
2.7 Study Timeline	No final --	No draft --	Add Delete

2.8. Enrollment of First Subject Please Select...

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Inclusion Enrollment Report 1 of 1 Delete This Inclusion Enrollment Report

⟨ 1 ⟩

1. *Using an Existing Dataset or Resource ◯ Yes ◯ No
2. *Enrollment Location Type ◯ Domestic ◯ Foreign

3. Enrollment Country(ies)

X Please Select...

Add New Country

4. Enrollment Location(s)

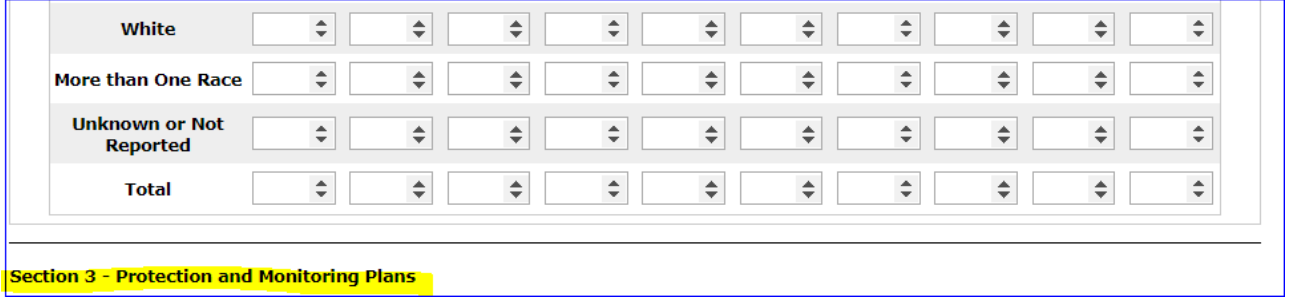
5. Comments

Planned

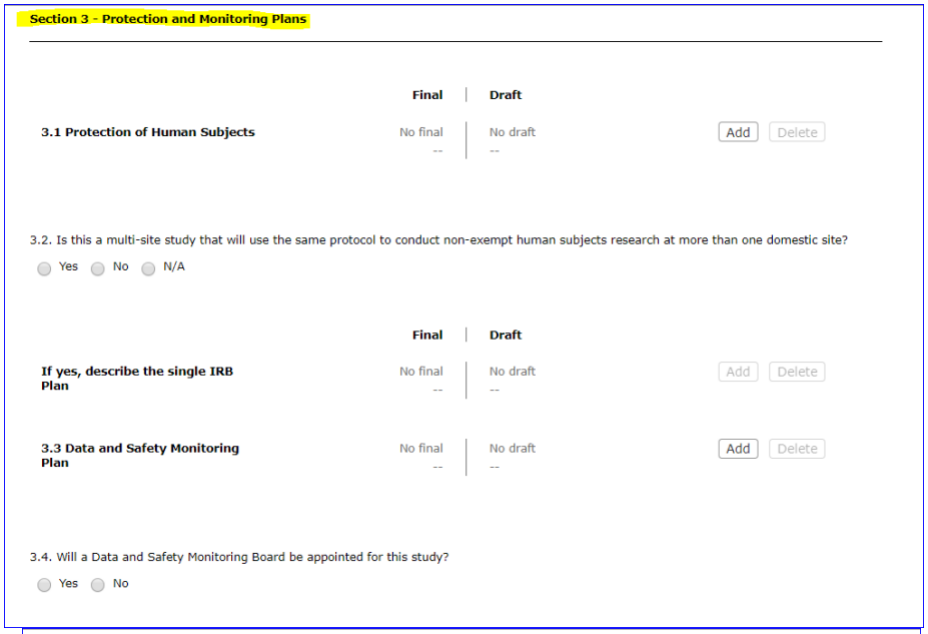
Racial Categories	Ethnic Categories: Not Hispanic or Latino Female	Not Hispanic or Latino Male	Hispanic or Latino Female	Hispanic or Latino Male	Total
American Indian/ Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One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

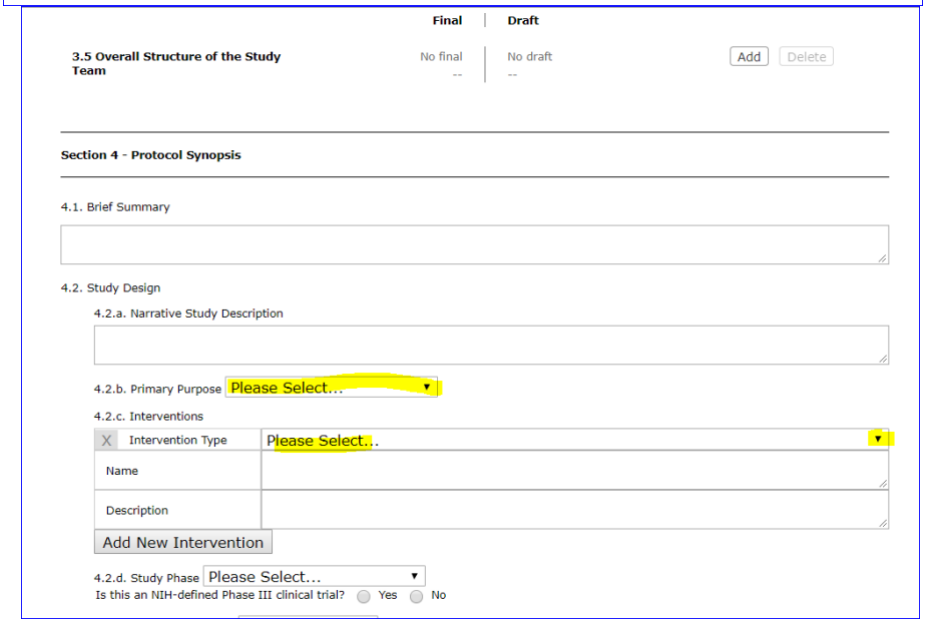
Actual

Racial Categories	Ethnic Categories: Not Hispanic or Latino Female	Male	Unknown/ Not Reported	Hispanic or Latino Female	Male	Unknown/ Not Reported	Unknown/Not Reported Ethnicity Female	Male	Unknown/ Not Reported	Total
American Indian/ Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										

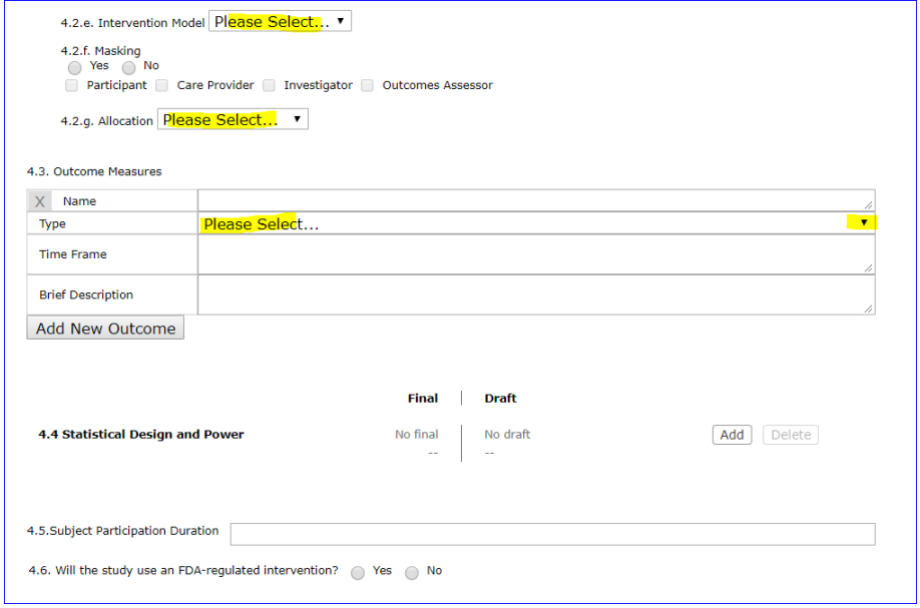


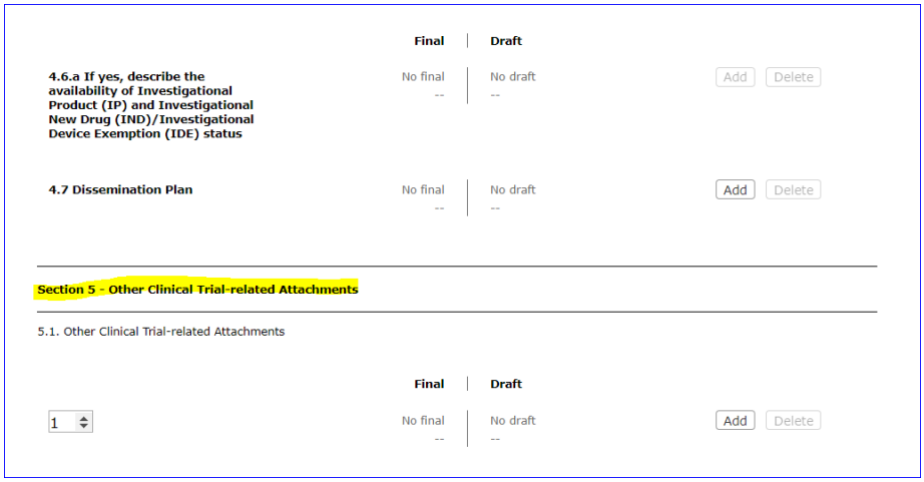
For **HUMAN SUBJECTS ONLY:** Respond to ALL questions and **STOP after 3.2** (Multi-Site question) is answered.
For **CLINICAL TRIALS ONLY**: Complete the rest of the application fields: 3.3-3.5, Section 4 and 5.





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





(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.