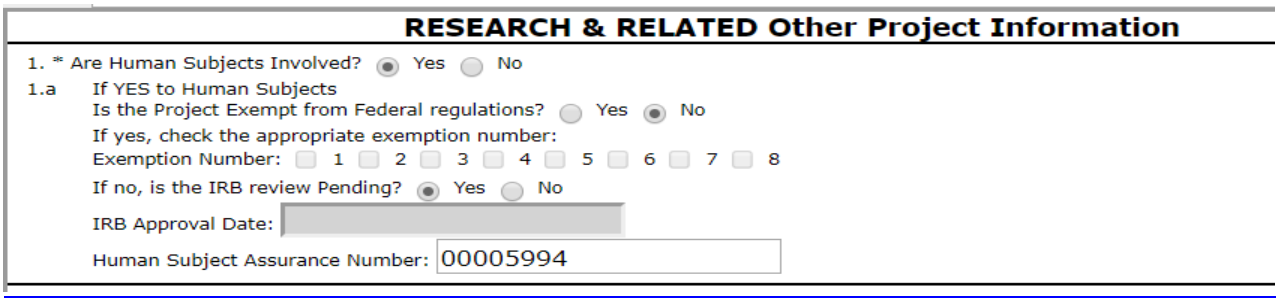
NIH Human Subjects and Clinical Trials (To be used after January 2018)

NIH has changed their data collection strategy, and some of the forms have been consolidated.
UH uses the CAYUSE system which is an independent system that interfaces with Grants.gov.
The PHS forms are imbedded in the CAYUSE system.
Please watch the Youtube video and follow the instructions below.

PHS HOW TO VIDEO YOUTUBE

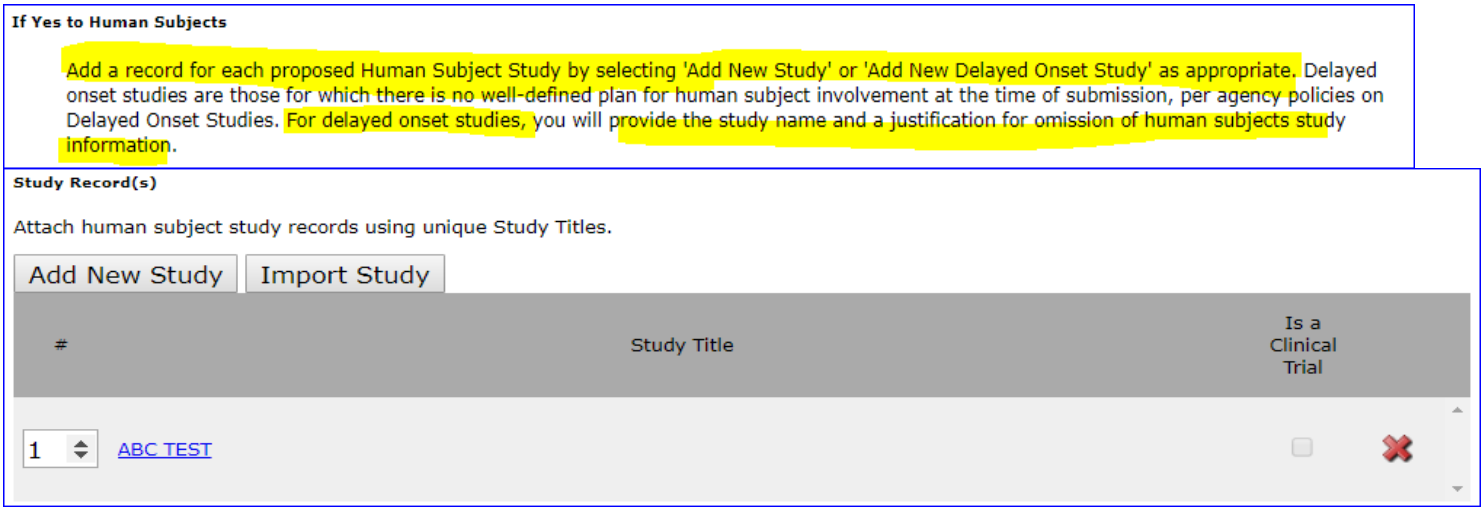
YOU Tube Human Subjects and Clinical Trials Information

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



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



(A) Full Study Record (5 sections)

The first four questions (1.4 a, b, c, d) under Human subject determine 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 --	Add 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? 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., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

X

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits Minimum Age Please Select... Maximum Age Please Select...

	Final	Draft	
2.4 Inclusion of Women, Minorities, and Children	No final --	No draft --	Add Delete
2.5 Recruitment and Retention Plan	No final --	No draft --	Add Delete

2.6. Recruitment Status Please Select...

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	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										
White										
More than One Race										
Unknown or Not Reported										
Total										

Section 3 - Protection and Monitoring Plans

For **HUMAN SUBJECTS**, 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 --	Add 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 --	Add Delete
3.3 Data and Safety Monitoring Plan	No final --	No draft --	Add Delete

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 --	Add Delete

Section 4 - Protocol Synopsis

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose Please Select...

4.2.c. Interventions

X Intervention Type	Please Select...
Name	
Description	

Add New Intervention

4.2.d. Study Phase Please Select...

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

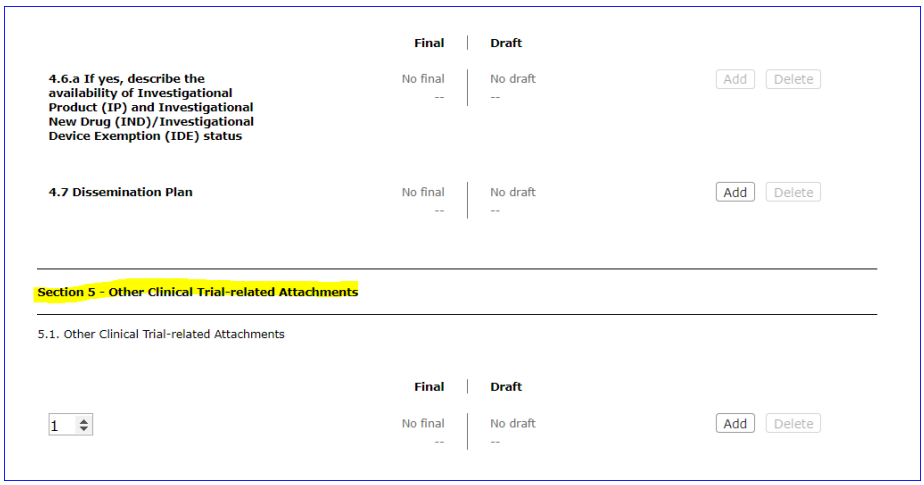
X Name	
Type	Please Select...
Time Frame	
Brief Description	

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



(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.

2022/dlm