InfoEd Human Subjects/Clinical Trials Page

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	
CS	Delete

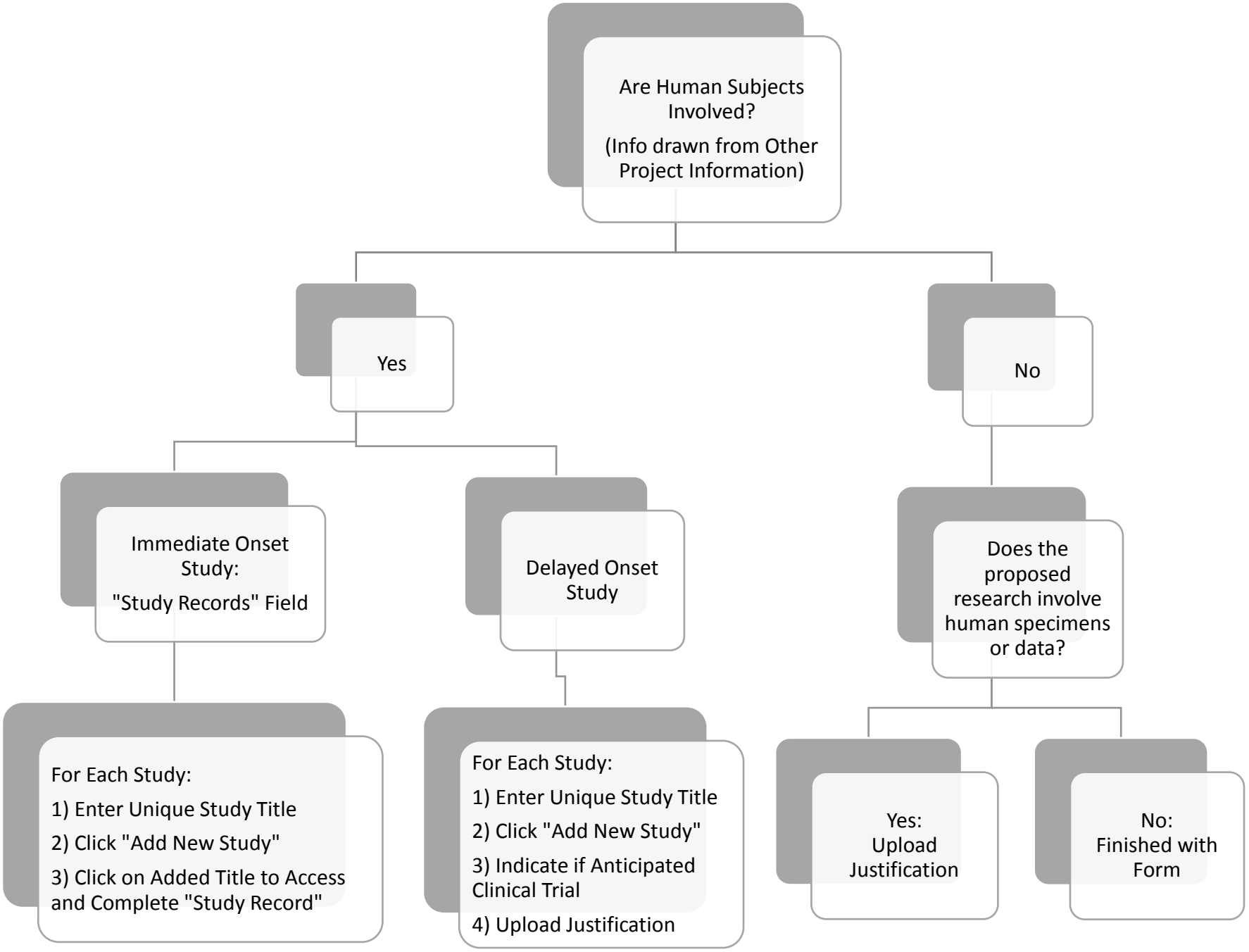
Enter Study Title (each study title must be unique) Add New Study

Delayed Onset Study(ies) [Hide]

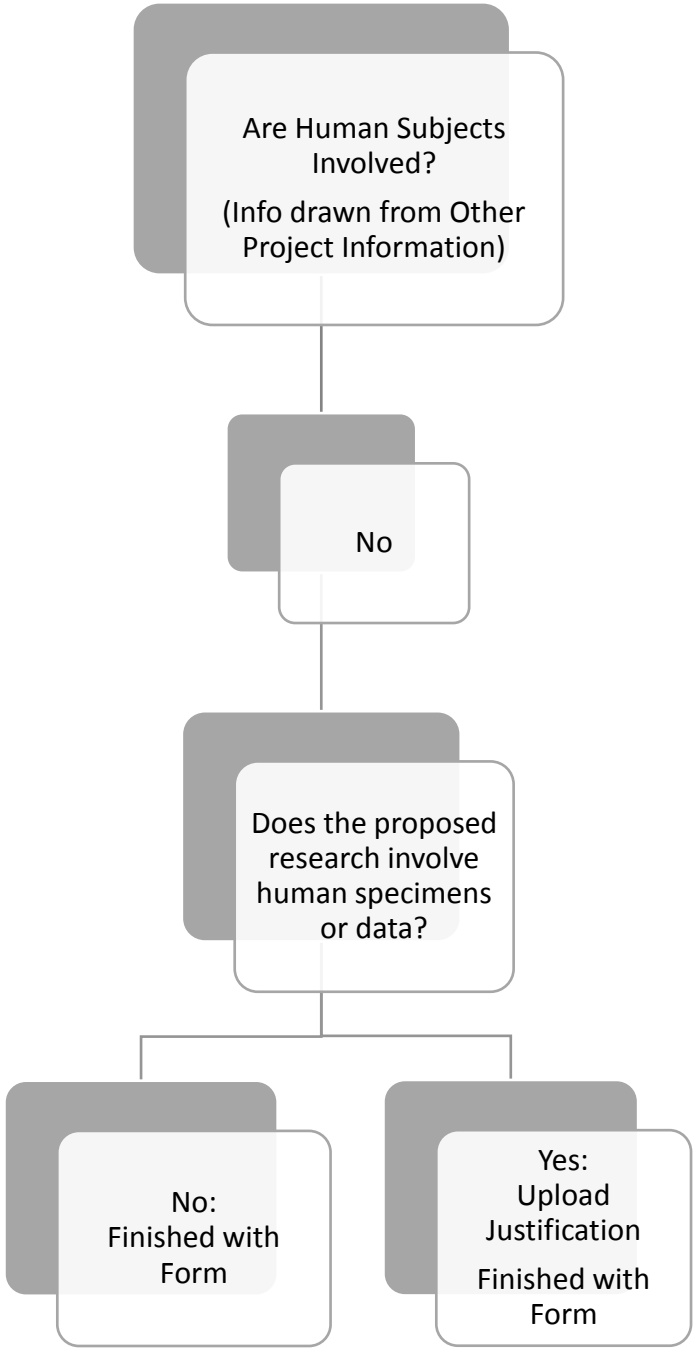
Study Title	Anticipated Clinical Trial?	Justification			
			Original	PDF	
Chris Study	☐	Upload			Delete

Enter Study Title (each study title must be unique) Add New Delayed Onset Study

PHS HUMAN SUBJECTS AND CLINICAL TRIALS FRONT PAGE OVERVIEW



PHS HUMAN SUBJECTS AND CLINICAL TRIALS FRONT PAGE: NO HUMAN SUBJECTS



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 ○

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

If No to Human Subjects

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

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

PHS HUMAN SUBJECTS AND CLINICAL TRIALS FRONT PAGE: HUMAN SUBJECTS RESEARCH

Are Human Subjects Involved?

YES

(Info drawn from Other Project Information)

Immediate Onset Study:

"Study Records" Field

Delayed Onset Study

For Each Study:

1.1) Enter Unique Study Title

1.2) Click "Add New Study"

1.3) Click on Added Title to Access and Complete "Study Record"

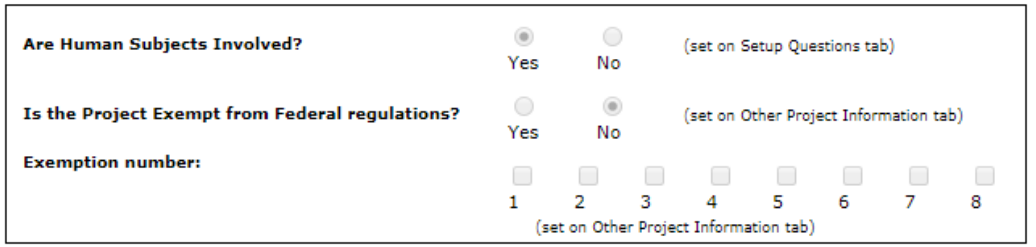
For Each Study:

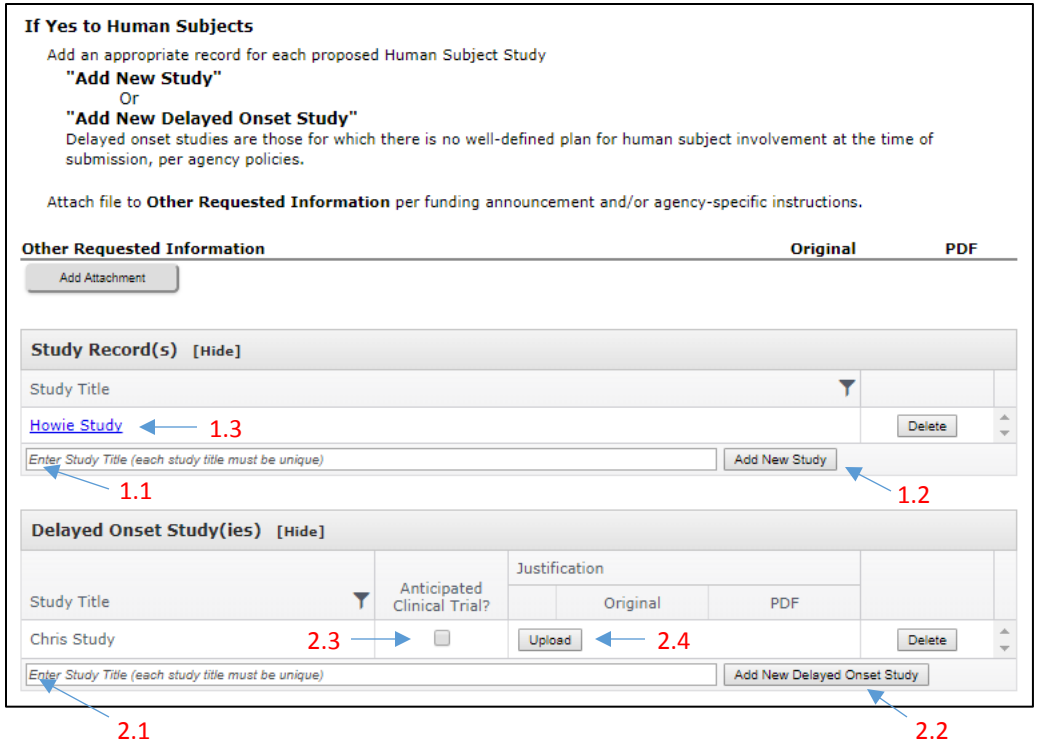
2.1) Enter Unique Study Title

2.2) Click "Add New Study"

2.3) Indicate if Study is Anticipated Clinical Trial (Only if Using "Clinical Trial Required" PA / RFA)

2.4) Upload Justification





The NIH defines a **Delayed Onset Study** as being: Any instance in which human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application. **In this case, use the Delayed Onset Study field.**

Any human subjects research that has been defined or designed before the award period begins and can be described in the application is considered an **Immediate Onset Study and will require the use of the Study Records Field**

COMPLETING THE STUDY RECORD: HUMAN SUBJECTS RESEARCH VS. CLINICAL TRIALS

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., NCT87654321) for this trial, if applicable