

PennERA - Proposal Development



NIH FORMS-F Human Subjects and Clinical Trials Info

Interest Areas: NIH S2S Submissions

A screen overview is provided below of the steps needed to complete the NIH Human Subjects and Clinical Trials Info form in PennERA. For more complete details, please refer to NIH's information on this topic:

- [Annotated Form Set for NIH Grant Applications - FORMS-F](#) (pages 31-37).
- NCT04161885NCT04161885 [NIH Application Guide - FORMS-F](#) (Section G.500, beginning page G.231).

Human Subjects/CT

After completing the form, click to check NIH's electronic validations.

Completed

OMB Number: 0925-0001
Expiration Date: 2/28/2023

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.

This section is required for ALL applications but applies only to Human Specimens and/or Data.

Use of Human Specimens and/or Data

*Does any of the proposal research in the application involve human specimens and/or data? Yes No

Provide an explanation for any use of human subjects and/or data not considered to be human subjects research.

Add Attachment

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

Information in this section is populated from the Other Project Information screen.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? Yes No

Is the Project Exempt from Federal regulations? Yes No

Exemption number:

Yes No

Yes No

1 2 3 4 5 6 7 8

If No to Human Subjects

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

Read this section to determine next steps.

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.

Other Requested Information

If the study is already registered at ClinicalTrials.gov, click "Import from ClinicalTrials.gov" to automatically add the study record.

Original

PDF

Add Attachment

Study Record(s) [Hide] Import from ClinicalTrials.gov

Study Title

No records to display.

If study is not delayed onset, enter unique Study Title, then click "Add New Study". Click on the created link (e.g., "Test Study 1") in order to complete the Study Record. Inclusion Enrollment Report is added from the Study Record.

Enter Study Title (each study title must be unique)

Add New Study

Delayed Onset Study(ies) [Hide]

Study Title

Anticipated Clinical Trial?

Justification

No records to display.

If study is delayed onset, enter unique Study Title, then click "Add New Study". After the study has been added, answer CT question and upload Justification document.

Enter Study Title (each study title must be unique)

Add New Delayed Onset Study

For assistance, please contact PennERA Help PennERAhelp@lists.upenn.edu.