An overview of the steps needed to complete the NIH Human Subjects and Clinical Trials Info form in PennERA. More detailed information can be found in the linked resources.

- A Walk Through of the PHS Human Subjects and Clinical Trial Form (NIH video, 9 minutes).
- Annotated Form Set for NIH Grant Applications - FORMS-E (pages 11-16).
- NIH Application Guide - FORMS-E (Section G.500, beginning page G.223).

Complete Human Subjects section of Other Project Info screen prior to completing this form. Information is populated from Other Project Info screen.

If Human Subjects is “No”, answer the question, provide Other Requested Information attachment (if applicable), and the form is done.

If Human Subjects is “Yes”, add Study Record(s) and or Delayed Onset Study(ies) below.

Check Application Guide and announcement to determine if attachment is needed.

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.

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.

Validate XML and NIH Pre-Submission

This form may be validated once it has been completed using the NIH Pre-Submission Validation Service (SVS).

- Click Validate XML & NIH Pre-Submission in the top right corner of the form.
- All mandatory data elements (fields and uploads) on all screens must be addressed in order to use this functionality.

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