Instructions for PI to Access PHS Human Subjects and Clinical Trials Information Form

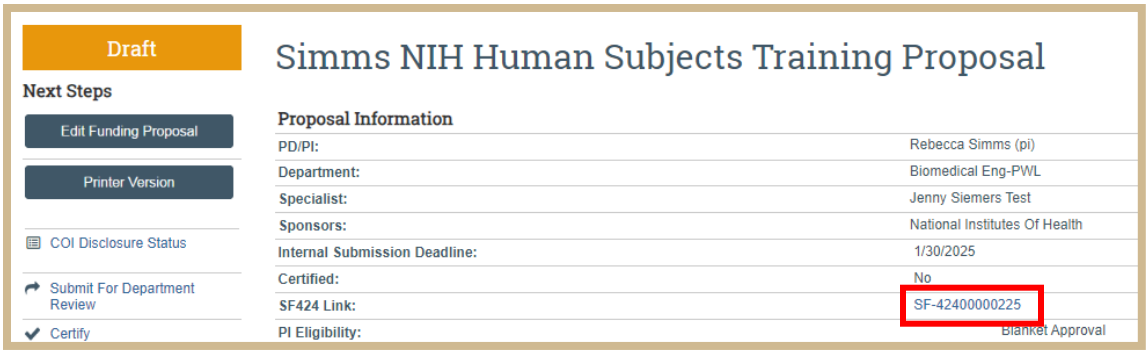
PHS Funding Proposals that include Human Subjects and Clinical Trial Research must include the PHS Human Subjects and Clinical Trials Information Form.

There is not a form set available for download that can be used to submit a grant application with System-to-System submission in PERA. Due to the complexity of this form, a PI must complete the requirement in the PERA SF424.

The following instructions detail how to access the Form for completion.

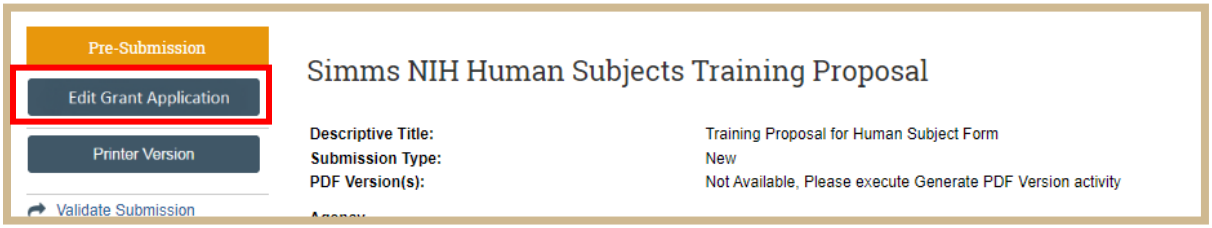
Access the SF424 From the Funding Proposal Workspace

1. The Pre-Award Specialist will create the SF424 from the Funding Proposal Workspace and notify the PI when the form can be completed.



2. From the SF424 Workspace, click the link to the SF-424.

3. The SF424 Workspace will open.



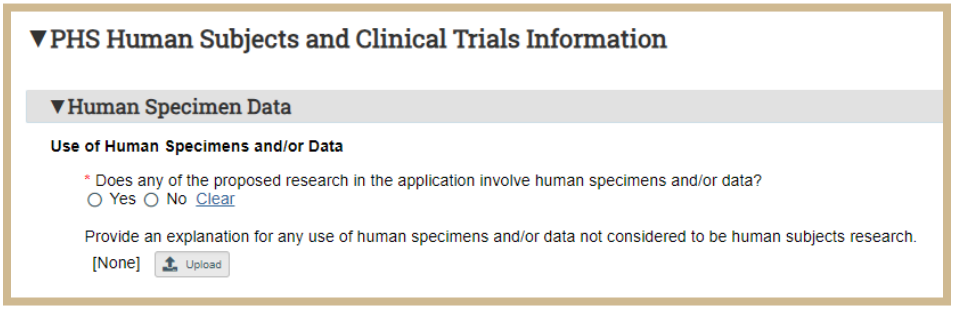
4. Select "Edit Grant Application from the SF424 Workspace.

All required forms for the submission will appear in the Navigation menu.

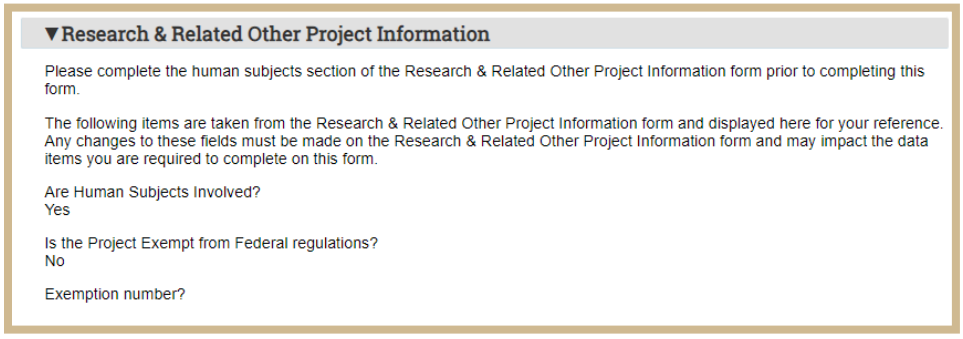
5. Select the "PHS Human Subjects and Clinical Trials Information" form.

6. The form will open with all applicable data fields. Complete the fields as outlined in the PHS instructions.

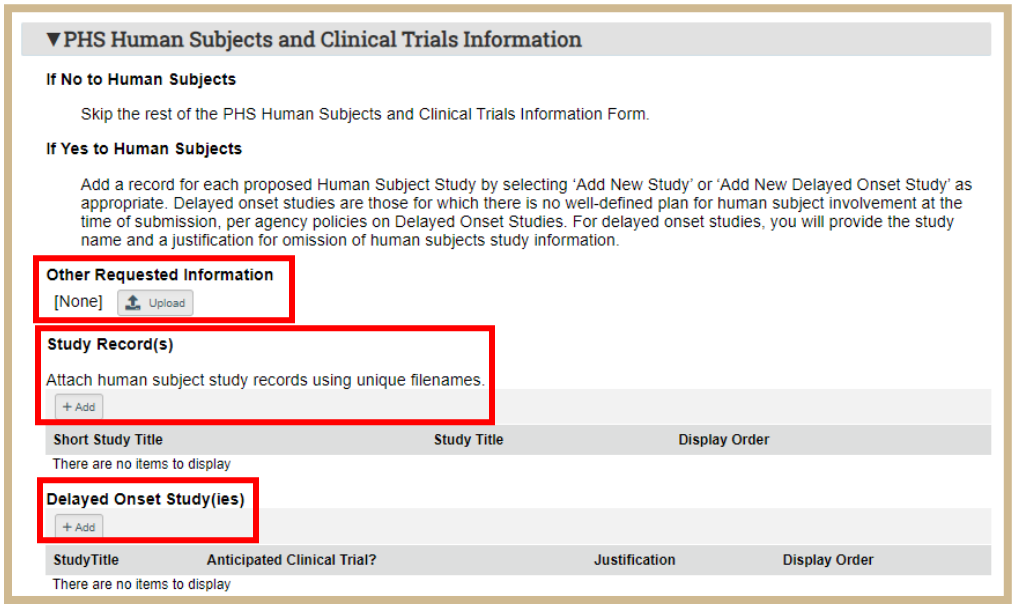
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.500-phs-human-subjects-and-clinical-trials-information.htm



7. Yes/No is Required for the Human Specimen Data Section.

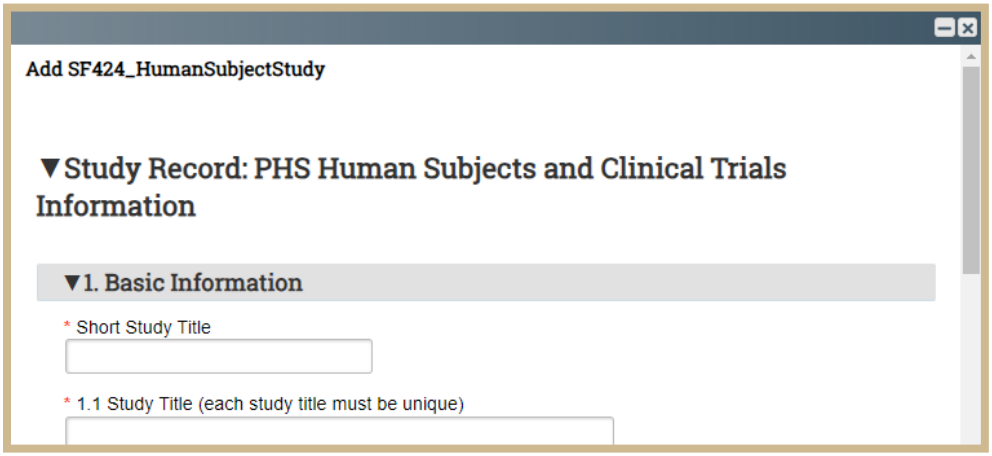


8. The Research & Related Other Project Information form is prepopulated with the information provided on the Funding Proposal SmartForm. If this information is incorrect, contact Pre-Award.

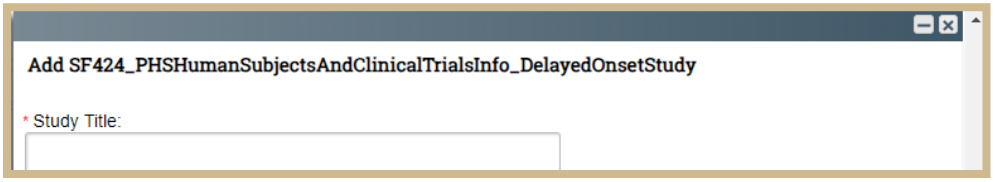


9. Add required attachments, Study Records, or Delayed Onset Forms. https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#Other

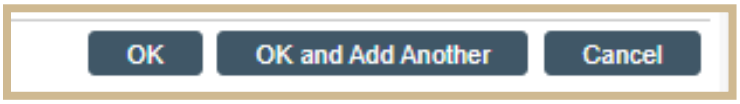
Study Record Form



Delayed Onset Form



10. After completing each required Study Record or Delayed Onset Form, select “OK” to Save or “OK and Add Another” if multiple Forms are needed.



11. When all forms are complete, Select “Save” then “Exit”. From the SF424 Workspace and exit the SF424.
Notify the Pre-Award Specialist when form is complete.