

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.

The screenshot shows a web interface for a funding proposal workspace. At the top left, there is a yellow 'Draft' label. Below it, a 'Next Steps' section contains buttons for 'Edit Funding Proposal', 'Printer Version', 'COI Disclosure Status', 'Submit For Department Review', and 'Certify'. The main content area is titled 'Simms NIH Human Subjects Training Proposal' and contains a 'Proposal Information' table.

Proposal Information	
PD/PI:	Rebecca Simms (pi)
Department:	Biomedical Eng-PWL
Specialist:	Jenny Siemers Test
Sponsors:	National Institutes Of Health
Internal Submission Deadline:	1/30/2025
Certified:	No
SF424 Link:	SF-4240000225
PI Eligibility:	Blanket Approval

2. From the SF424 Workspace, click the link to the SF-424.
3. The SF424 Workspace will open.

Pre-Submission

Edit Grant Application

Printer Version

Validate Submission

Simms NIH Human Subjects Training Proposal

Descriptive Title: Training Proposal for Human Subject Form
Submission Type: New
PDF Version(s): Not Available, Please execute Generate PDF Version activity

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

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

Validate Compare

Select Optional Forms

- SF424 R&R Cover Page V5.0
- Project/Performance Site Location(s) V4.0
- Research & Related Other Project Information V1.4
- Research & Related Senior/Key Person Profile (Expanded) V4.0
- PHS 398 Cover Page Supplement V5.0
- PHS 398 Research Plan V5.0
- PHS Human Subjects and Clinical Trials Information V3.0**

End Of Form Pages

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>

▼ PHS Human Subjects and Clinical Trials Information

▼ Human Specimen Data

Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data?
 Yes No [Clear](#)

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.
[None]

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

▼ Research & Related Other Project Information

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

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

Is the Project Exempt from Federal regulations?
No

Exemption number?

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.

▼ PHS Human Subjects and Clinical Trials Information

If No to Human Subjects

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

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
[None]

Study Record(s)
Attach human subject study records using unique filenames.

Short Study Title	Study Title	Display Order
There are no items to display		

Delayed Onset Study(ies)

StudyTitle	Anticipated Clinical Trial?	Justification	Display Order
There are no items to display			

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

Add SF424_HumanSubjectStudy

▼ Study Record: PHS Human Subjects and Clinical Trials Information

▼ 1. Basic Information

* Short Study Title

* 1.1 Study Title (each study title must be unique)

Delayed Onset Form

Add SF424_PHSHumanSubjectsAndClinicalTrialsInfo_DelayedOnsetStudy

* Study Title:

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.

OK OK and Add Another Cancel

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.

Exit Save Continue