Kuali FAQ - How to Complete Human Subjects Forms for NIH Submissions

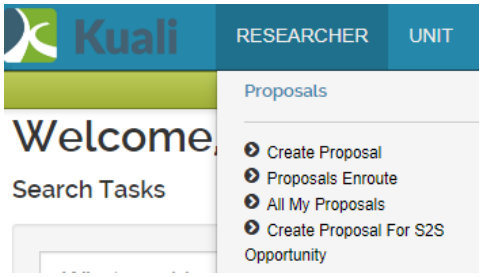
Earlier this year, the U.S. Department of Health and Human Services implemented Forms-E for National Institutes of Health and other Public Health Service Agencies. This revision contains a number of changes that apply to proposals involving Human Subjects and/or Clinical Trials. As NIH proposals are submitted system-to-system (S2S) via our online grants management system Kuali Research, there are new steps that must be taken in Kuali to ensure that all Human Subjects-related fields align with eRA Commons for an error-free submission.

How do I add a compliance entry for proposals Involving Human Subjects?

Most proposals involving Human Subjects will require IRB approval. Adding the compliance entry will notify the Compliance Coordinator and will automatically populate to the required fields in the S2S form.

1. Log-in to Kuali (https://siue.kuali.co/res).

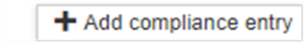
2. Find your proposal (Click **Researcher**, then **All My Proposals**)



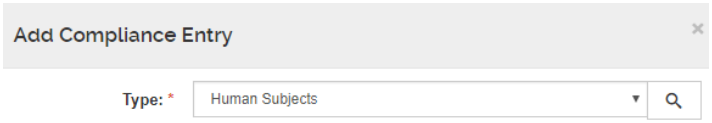
3. Scroll down and click **edit** next to your Proposal Number.

4. On the left, click on Compliance.

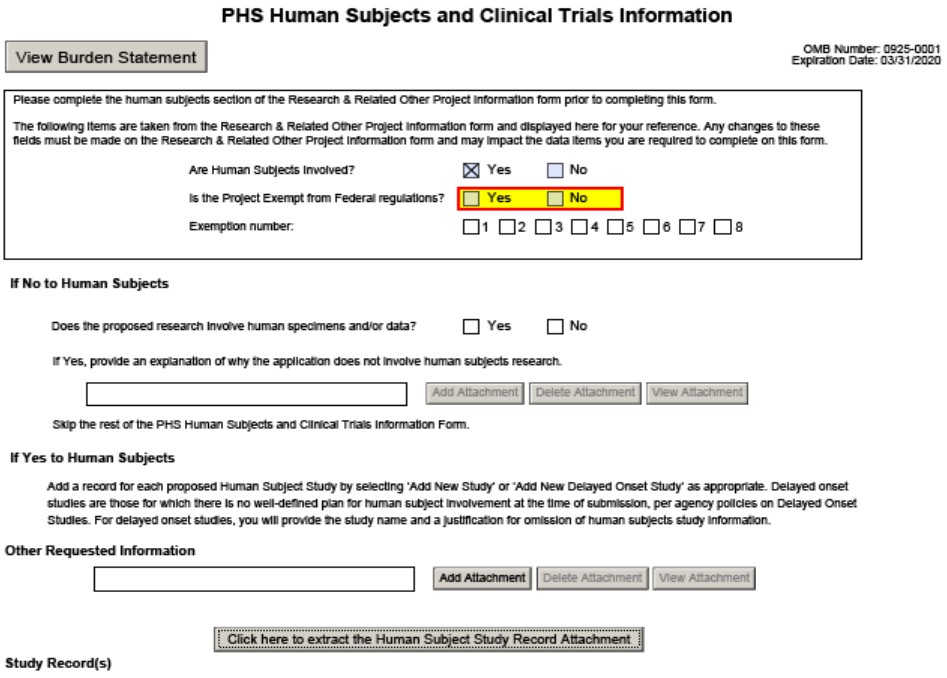
5. Click Add compliance entry.



6. For **Type**, select Human Subjects.



7. The **Compliance** entry for Human Subjects will now map to the appropriate fields as listed on the PHS Human Subjects and Clinical Trials Information form. (Screenshot of this form below).



PHS Human Subjects and Clinical Trials Information

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 03/31/2020

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 ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

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 | Delete Attachment | View Attachment

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.

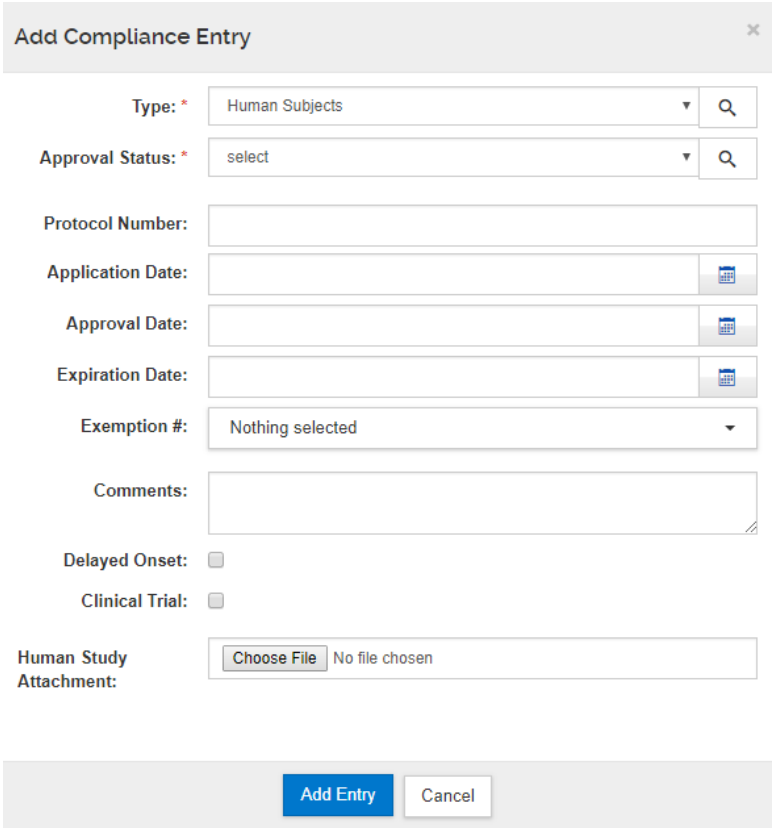
Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

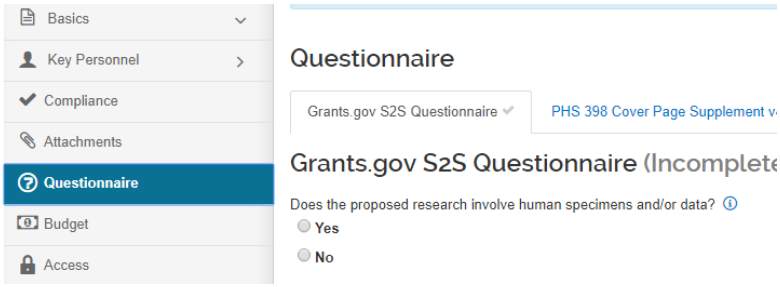
Study Record(s)

8. For **Approval Status**, select Not yet applied or Pending, if applicable.

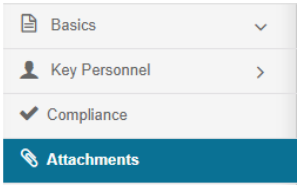


9. Select any Exemption Numbers, if applicable. (Click the link for more information)
10. Select the Delayed Onset or Clinical Trial box(es), if applicable.
11. **Study Record Attachment**
    - You can obtain the Human Study Record Attachment, HumanSubjectStudy-V1.0, by clicking the link. Instructions on filing out this form are in the ***Completing the Human Study Record*** section of this FAQ.
    - If your Human Study Record is complete and all embedded attachments are complete, you may upload this file by selecting “Choose File”.
    - If your Human Study Record is incomplete, you may upload this file as a placeholder by selecting “Choose File”. **Ensure that you upload the completed Human Study Record before submission.**
12. Click Add Entry.
13. Click Save.

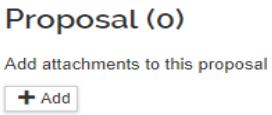
Do I need to complete the *Human Specimens – Justification For No Human Subjects* attachment?
Within the **Questionnaire** section of Kuali, if you answered yes to the question: "Does the proposed research involve human specimens and/or data?" on the **Grants.gov S2S Questionnaire tab,** but *no Human Subjects are involved*, you will be required to upload a justification as to why your application does not involve human subjects research. If human subjects are involved (as indicated by the Compliance entry added above), then this attachment is not required.



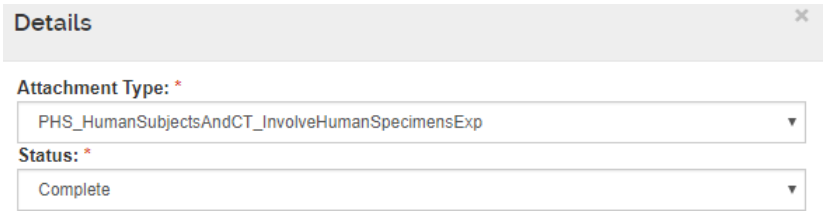
1. The justification should include: (See p.228-229 of General Forms-E for further guidance).
    - information on who is providing the data/biological specimens and their role in the proposed research;
    - a description of the identifiers that will be associated with human specimens and data;
    - a list of who has access to subjects' identities; and
    - information about the manner in which the privacy of research participants and confidentiality of data will be protected.
2. To upload this attachment, click Attachments.



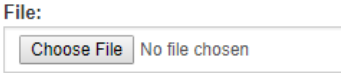
3. Click Add.



4. Under **Attachment Type,** select PHS_HumanSubjectsAndCT_InvolveHumanSpecimensExp. Under **Status**, select Complete.



5. Click Choose File to upload the PDF of your justification.

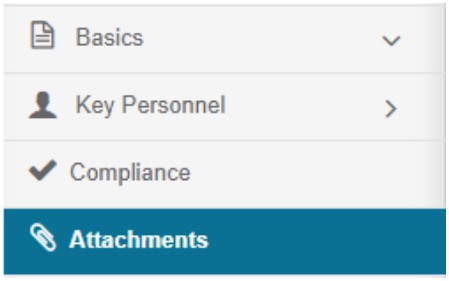


6. Click Save.

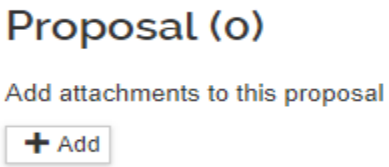
How do I complete the *Human Subjects - Other Requested Information* attachment?

In some circumstances, you will also be required to add the Other Requested Information attachment. For guidance on what to include in the Other Requested Information attachment, please see the instructions in your specific FOA.

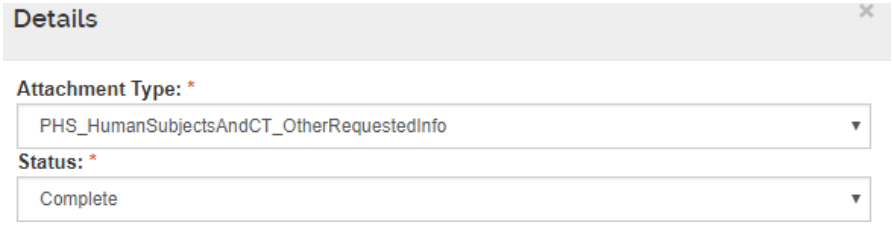
1. To upload your Other Requested Information attachment, on the left of the screen, click on Attachments.



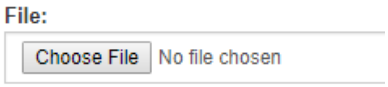
2. Click Add.



3. Under **Attachment Type,** select PHS_HumanSubjectsAndCT_OtherRequestedInfo. Under **Status**, select Complete.



4. Click Choose File to upload the PDF of your Other Requested Information attachment.



5. Click Save.

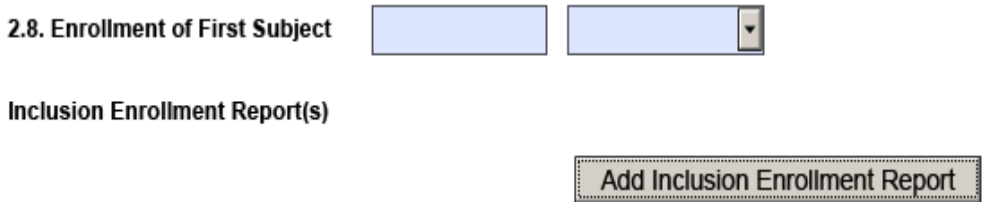
How do I complete the *Human Study Record*?

For further instructions on completing this form and its attachments, see Page 232 of the NIH General Forms E. To download the Human Study Record form, click here.

If your proposal involves Human Subjects, but not a Clinical Trial, complete all questions up to and including Question 3.2 of Human Study Record.

Complete the following attachments and add the attachment to the corresponding section within the Human Study Record:

- 2.4: Inclusion of Women, Minorities, and Children Policy (General Forms E, p. 236)
- 2.5: Recruitment and Retention Plan (General Forms E, p. 238)
- 2.7: Study Timeline (General Forms E, p. 239)
- Inclusion Enrollment Report (General Forms E, p. 240-245)
    - This report describes the anticipated demographics of your study population.
    - Within the Human Study Record, click Add Inclusion Enrollment Report and fill out the form completely.



- 3.1: Protection of Human Subjects Policy (General Forms E, p. 245-248)

If your proposal involves Human Subjects and a Clinical Trial, complete the Human Study Record in its entirety.

Complete the following attachments and Add Attachment to the corresponding question:

- 2.4: Inclusion of Women, Minorities, and Children Policy (General Forms E, p. 236)
- 2.5: Recruitment and Retention Plan (General Forms E, p. 238)
- 2.7: Study Timeline (General Forms E, p. 239)
- Inclusion Enrollment Report (General Forms E, p. 240-245)
- 3.1: Protection of Human Subjects Policy (General Forms E, p. 245-248)
- 3.3: Data and Safety Monitoring Plan (General Forms E, p. 250-251)
- 3.5: Overall Structure of the Study Team (General Forms E, p. 252)
- 4.3: Outcome Measures (General Forms E, p. 255)
- 4.4: Statistical Design and Power (General Forms E, p. 255-256)
- 4.7: Dissemination Plan (General Forms E, p. 256-257)