QUICK GUIDE
PHS HUMAN SUBJECTS & CLINICAL TRIALS INFORMATION
NIH HUMAN SUBJECT STUDY RECORD ATTACHMENT

Overview:
This guide will address how this form is populated under different scenarios: not human subject research; not human subject research but involves human specimens/data; and human subject research (with or without clinical trials).

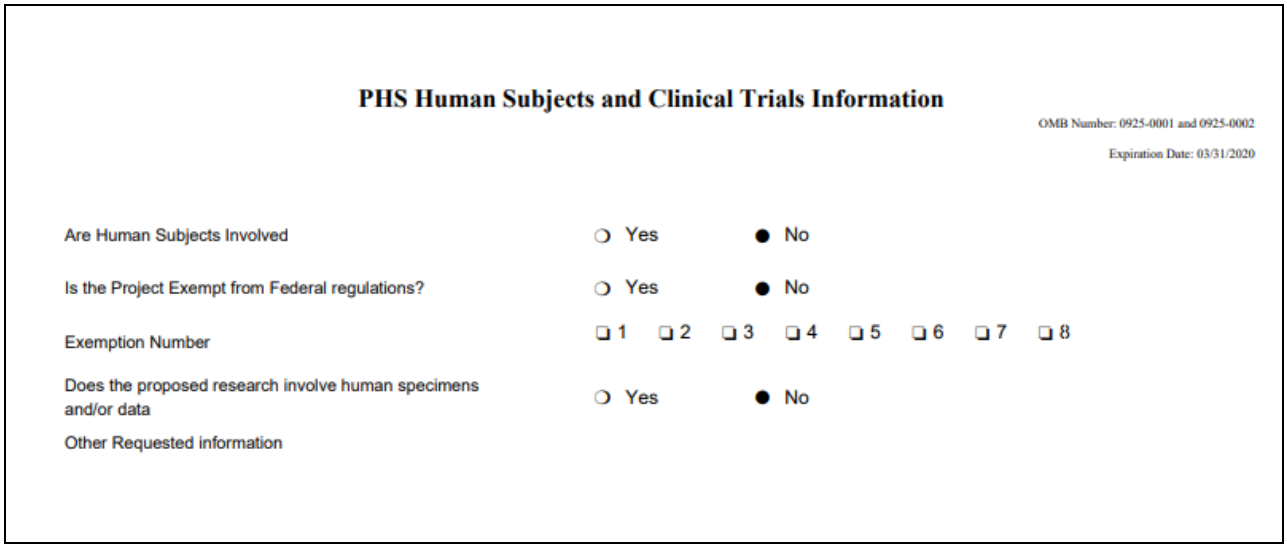
To start: All National Institutes of Health (NIH) funding opportunity announcements (FOAs) list whether they allow, require, or disallow clinical trials in the FOA's title and in "Section II. Award Information." You must select an FOA (solicitation) that accepts the type of research you wish to propose. Normally this is communicated clearly in the solicitation (FOA). For the Parent R01 solicitations, the options are expressed as follows:

- NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- NIH Research Project Grant (Parent R01 Clinical Trial Required)

Depending on the solicitation selected, and the responses provided in the "Grants.gov S2S Questionnaire" and the Compliance section, Kuali will validate accordingly.

➢ **For proposals that <u>do not</u> include human subject research (and therefore do not also involve clinical trials), there are two scenarios:**

Scenario #1
If no human subjects, data, or human subject specimens are planned:
- Correlate to the correct solicitation (Clinical Trial Not Allowed)
- Grants.gov S2S Questionnaire: Answer **No** to whether or not human specimens or data is involved
- Compliance panel: Do not include a Human Subject option
- Job done. These responses map to the sponsor form set and when printed it will look like this:



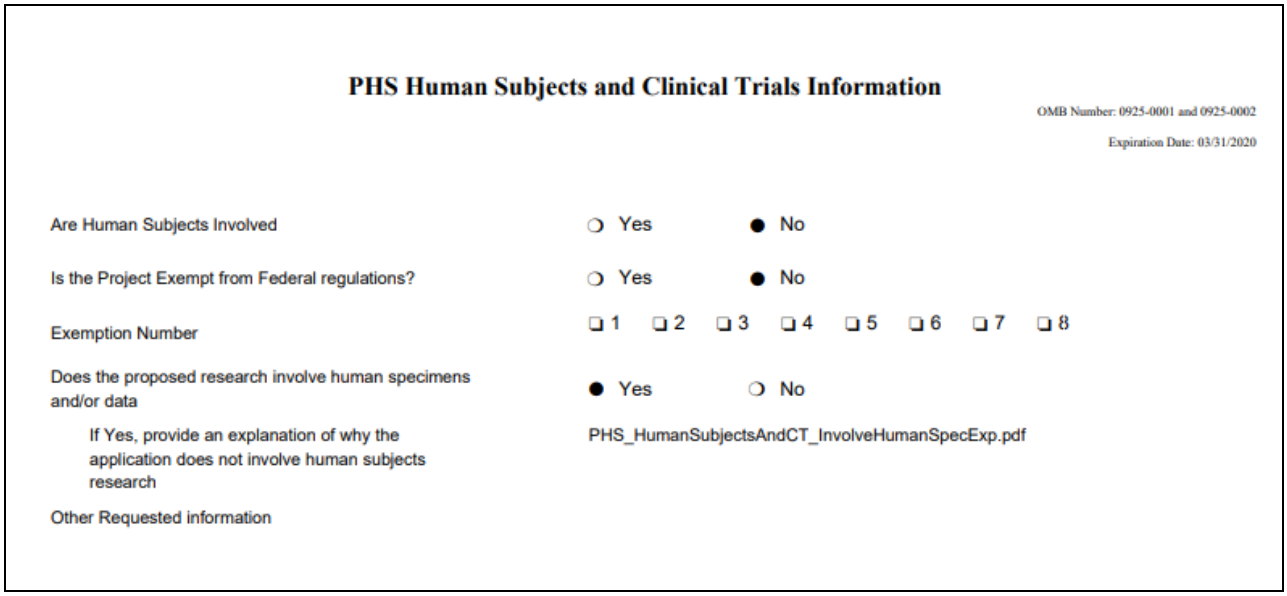
PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

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	
Does the proposed research involve human specimens and/or data	○ Yes	● No
Other Requested information		

Scenario #2:
If human subject data, or human subject specimens are planned, and the correct solicitation was selected (Clinical Trial Not Allowed):

- Grants.gov S2S Questionnaire: Answer **Yes** to whether or not human specimens or data is involved
- Compliance panel: Do not include a Human Subject option
- Human Subjects Explanation attachment is required for the Human Subjects Clinical Trials form when human specimens and/or data are involved. Select **Attachments** and then **Proposal** and load a document type **PHS_HumanSubectsAndCT_InvolveHumanSpecExp.** For help with this document, see the GENERAL INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES
- Job done. These responses map to the NIH formset and when printed it will look like this:



PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

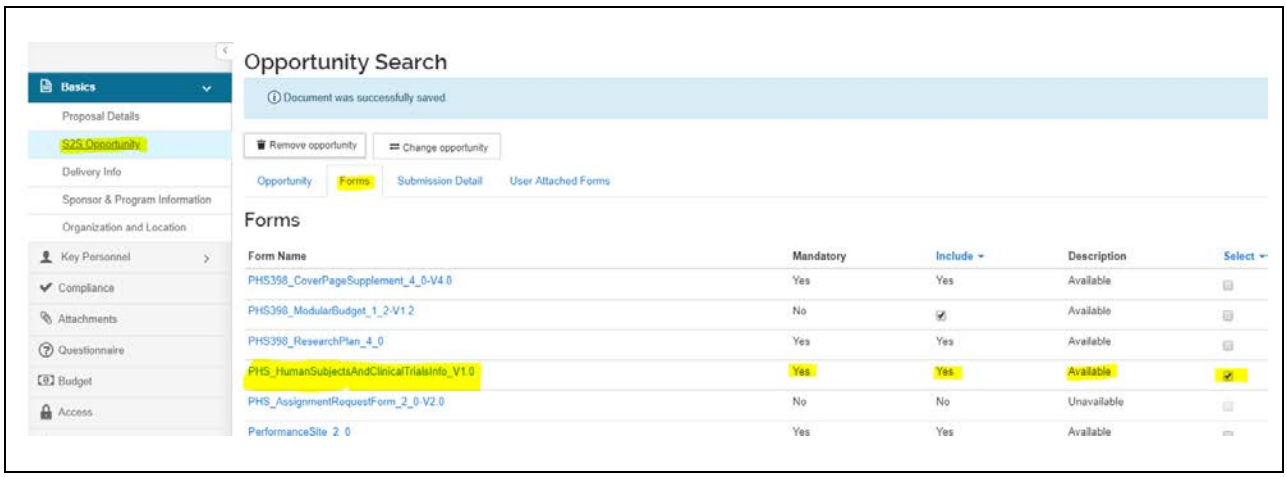
Are Human Subjects Involved	○ Yes ● No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Does the proposed research involve human specimens and/or data	● Yes ○ No
If Yes, provide an explanation of why the application does not involve human subjects research	PHS_HumanSubjectsAndCT_InvolveHumanSpecExp.pdf
Other Requested information	

➢ **For proposals that <u>do</u> include human subject research:**

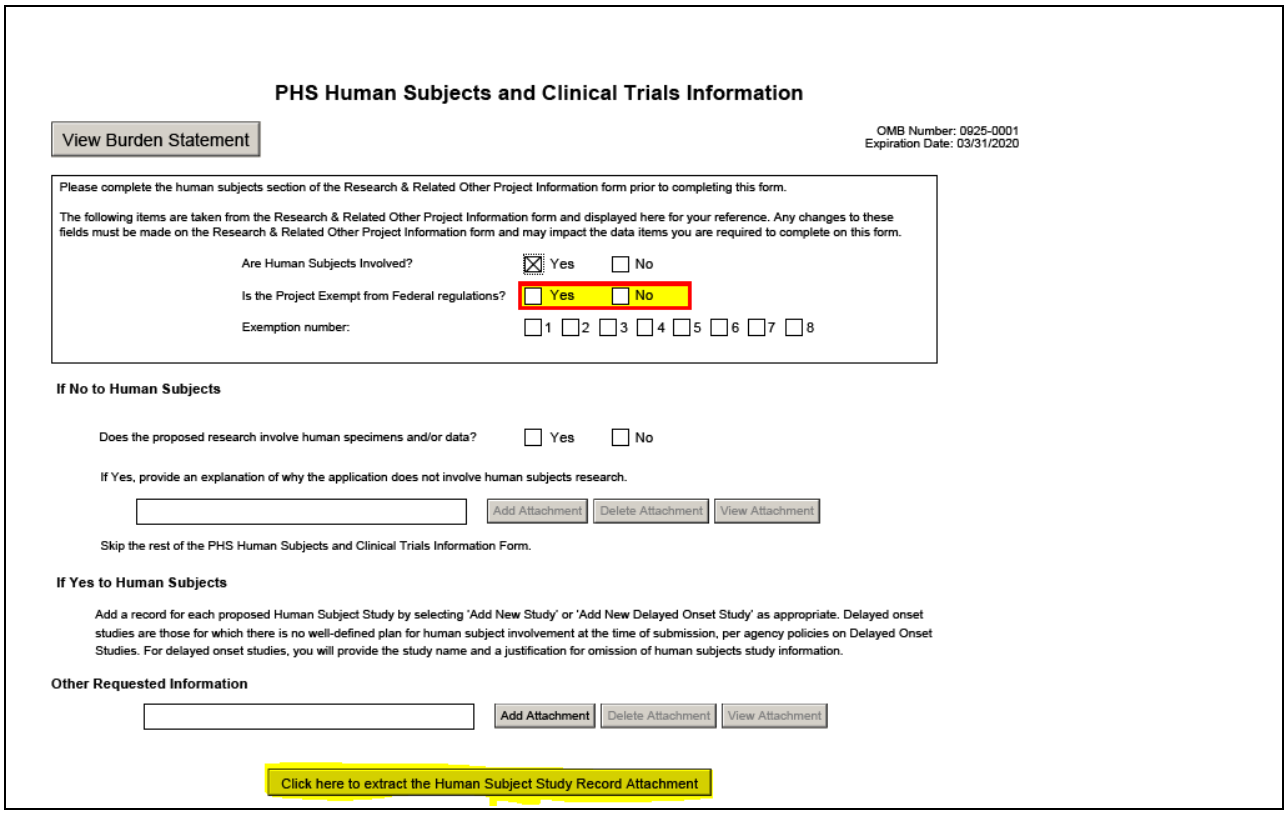
Scenario #3: Overview

- **S2S Opportunity**: Correlate the appropriate solicitation to the proposal based on whether the research qualifies as a clinical trial or not.
- Extract a **Human Subject Study Record** from the **PHS Human Subjects and Clinical Trials Information Form – save to desktop, complete.**
- **Grants.gov S2S Questionnaire**: Answer **Yes** to whether or not human specimens or data is involved
- **Compliance** panel: Include a **Human Subject** option from the compliance **Type** dropdown. Next, from the **Approval Status** dropdown, select **Pending**.
    - If **Delayed Onset** is applicable, check that box
    - If **Clinical Trial** is applicable, check that box
    - Select the **Human Study Attachment** browser and upload the completed **Human Subject Study Record**

STEP 1 – Navigate to the **Basics** section in Kuali. Enter the **S2S Opportunity** page and select the **Forms** tab. Here you will see that the **PHS Human Subjects and Clinical Trials Information** form is marked Mandatory, Included, and Available.



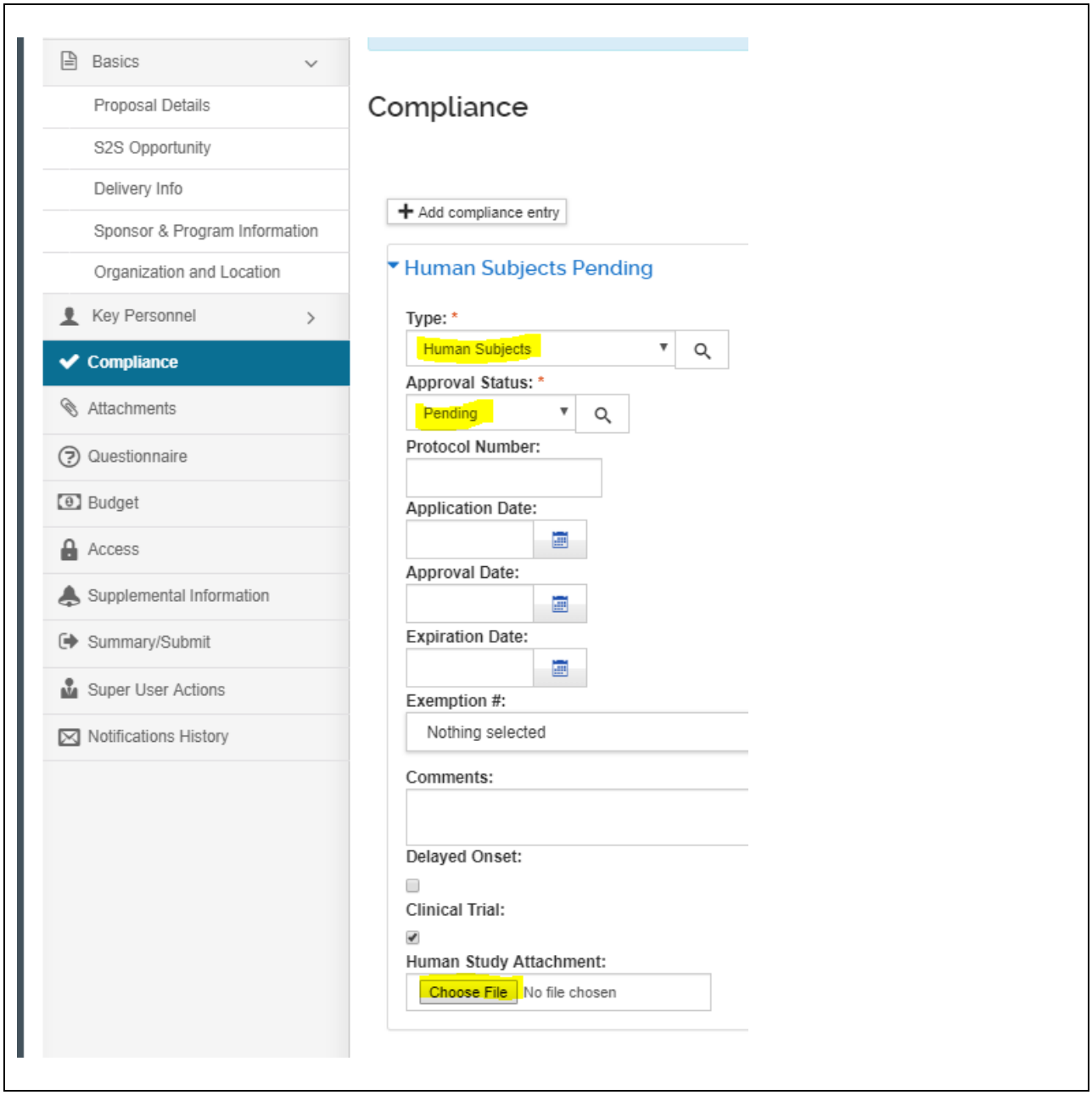
- Click on the highlighted form link and save the document to your desktop
- Open this form
- In order to access the **Human Subject Study Record** form, select **Yes** to the question "Are Human Subjects Involved?"
- This activates the ability to download the document – select **Click here to extract the Human Subject Study Record Attachment.**



- Complete the **Human Subject Study Record** form following the NIH Guidelines for Study Records; save to your desktop

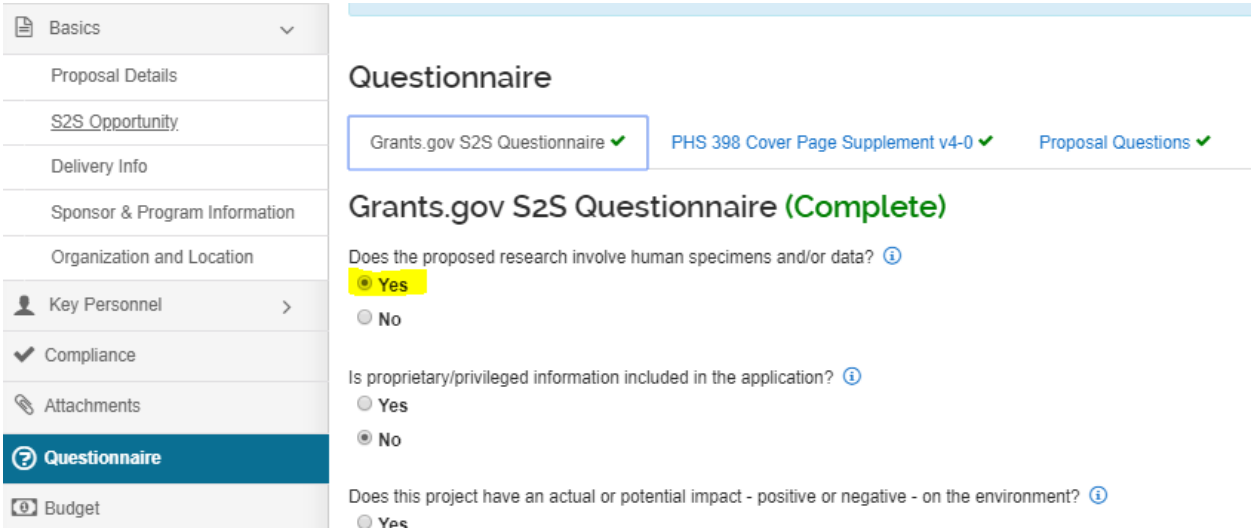
STEP 2 – Navigate to the **Compliance** section in Kuali.

- Select +**Add compliance entry** and choose **Human Subjects** from the **Type** dropdown
- Select **Pending** from the **Approval Status** dropdown
- Select **Delayed Onset** or **Clinical Trial** as applicable
- Select the **Human Study Attachment** browser
- Upload the completed Human Subject Study Record and click **Save and Continue**



STEP 3 – Complete the **Grants.gov S2S Questionnaire**

- Answer **Yes** to **Does the proposed research involve human specimens and/or data?**



All of the above steps will lead to a successful validation of a proposal that includes human subject research.
Job done.

GET HELP

KUALI KNOWLEDGE BASE:
https://kuali-research.zendesk.com/hc/en-us/articles/115014929747-S2S-PHS-HumanSubjectsAndClinicalTrialsInfo-Form-Instructions

https://kuali-research.zendesk.com/hc/en-us/articles/115015653708-Proposal-Compliance

KUALI GUIDES: https://www.umass.edu/research/kuali-guides

KUALI FAQs: https://www.umass.edu/research/kuali-research-faq

KUALI HELPDESK: https://www.umass.edu/research/webform/kuali-help-desk

NIH:
https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

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