

## 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 do not 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	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Is the Project Exempt from Federal regulations?	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Exemption Number	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8		
Does the proposed research involve human specimens and/or data	<input type="radio"/> Yes <input checked="" type="radio"/> 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\_HumanSubjectsAndCT\_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	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is the Project Exempt from Federal regulations?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Exemption Number	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8
Does the proposed research involve human specimens and/or data	<input checked="" type="radio"/> Yes <input type="radio"/> 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 do 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 Subject 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.

Opportunity Search

Document was successfully saved

Remove opportunity Change opportunity

Opportunity **Forms** Submission Detail User Attached Forms

Form Name	Mandatory	Include	Description	Select
PHS398_CoverPageSupplement_4_0-V4.0	Yes	Yes	Available	
PHS398_ModularBudget_1_2-V1.2	No	<input checked="" type="checkbox"/>	Available	
PHS398_ResearchPlan_4_0	Yes	Yes	Available	
<b>PHS_HumanSubjectsAndClinicalTrialsInfo_V1.0</b>	<b>Yes</b>	<b>Yes</b>	<b>Available</b>	<input checked="" type="checkbox"/>
PHS_AssignmentRequestForm_2_0-V2.0	No	No	Unavailable	
PerformanceSite 2.0	Yes	Yes	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**.

**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.

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**

[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**

The screenshot shows the Kuali Compliance form interface. On the left is a sidebar menu with the following items: Basics (expanded), Proposal Details, S2S Opportunity, Delivery Info, Sponsor & Program Information, Organization and Location, Key Personnel, Compliance (selected), Attachments, Questionnaire, Budget, Access, Supplemental Information, Summary/Submit, Super User Actions, and Notifications History. The main content area is titled 'Compliance' and features a '+ Add compliance entry' button. Below this, a section titled 'Human Subjects Pending' contains the following fields: 'Type' (dropdown menu with 'Human Subjects' selected), 'Approval Status' (dropdown menu with 'Pending' selected), 'Protocol Number' (text input), 'Application Date' (calendar icon), 'Approval Date' (calendar icon), 'Expiration Date' (calendar icon), 'Exemption #' (text input with 'Nothing selected'), 'Comments' (text area), 'Delayed Onset' (checkbox), 'Clinical Trial' (checkbox), and 'Human Study Attachment' (file upload button labeled 'Choose File' with 'No file chosen' text).

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

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

The screenshot shows a web interface for completing the Grants.gov S2S Questionnaire. On the left is a sidebar menu with options: Basics, Proposal Details, S2S Opportunity, Delivery Info, Sponsor & Program Information, Organization and Location, Key Personnel, Compliance, Attachments, Questionnaire (highlighted), and Budget. The main content area is titled 'Questionnaire' and shows three status indicators: 'Grants.gov S2S Questionnaire' with a green checkmark, 'PHS 398 Cover Page Supplement v4-0' with a green checkmark, and 'Proposal Questions' with a green checkmark. Below this, the title 'Grants.gov S2S Questionnaire (Complete)' is displayed in green. Three questions are listed: 'Does the proposed research involve human specimens and/or data?' with 'Yes' selected (highlighted in yellow), 'Is proprietary/privileged information included in the application?' with 'No' selected, and 'Does this project have an actual or potential impact - positive or negative - on the environment?' with 'Yes' selected.

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>