

KUALI QUICK GUIDE

NOT HUMAN SUBJECTS RESEARCH

I. GENERAL INSTRUCTIONS

- A. This Quick Guide applies to:** Preparation of a new protocol to request a determination whether an activity is Human Subjects Research (HSR) or is Not Human Subjects Research (NHSR).
- B. More Information:** The definition of HSR and examples of activities that are NHSR is available at the [IRB website](#).
- C. Navigation:**
 - a. In order to move through the smart form, you must complete all sections within the General Information Page, starting with the Study Identification section. Once you have completed all sections, press “**Next**” to continue with the NHSR Questionnaire section.
- D. Attachments:** There are no specific document requirements for research not subject to human subjects regulations. However, if you need to upload one or more documents associated with this submission, you can do so in the Supporting Documents Sections.
- E. New Protocol Overview:** Reference this quick guide found on our [Kuali Quickguide webpage](#) for an overview and additional guidance related to each section.

II. GENERAL INFORMATION PAGE

- A. Study Identification:**
 - a. **Title:** Enter the title of your study.
 - b. **Principal Investigator:**
 - i. Begin typing the first or last name of the PI and candidates will automatically appear from the list of users in Kuali.
 - ii. Click the PI’s name and it will be entered in the field.
 - c. **Department:** Primary appointment of PI
 - i. Begin typing the name of the department and candidates will automatically appear from the list of departments stored in Kuali.
 - ii. Click the department’s name and it will be entered in the field.
 - d. **School:** Select the School from the drop-down list that corresponds to the primary appointment of the PI.
 - e. Press “**Next**”
- B. Level of Review:**
 - a. Select the “**Protocol Type**” from the drop down menu: **Not Human Subjects Research**
 - b. Press “**Next**”

III. PROTOCOL TYPE QUESTIONNAIRE SECTION

A. Questionnaire: Not Human Subjects Research

The NHSR questionnaire is divided into four basic Steps (a-d) in which information is required.

- a. **Project summary:** Provide a brief summary of the project
- b. **Activities that are NHSR:** This section contains a list of activities generally considered to be NHSR. Select any activity(ies) that apply to the proposed project.
 - i. If your project is limited to one or more of these activities and all conditions for select activities are met, you will be asked to provide any supporting documents and then submit the protocol.
 - ii. If your project is not limited to one or more of these activities or all conditions are not met, you will proceed to the Step c.
- c. **Research Determination:** The questions in this section are designed to evaluate if your project meets the regulatory definition of “Research.” Answer all questions.
 - i. Under some circumstances, an activity that is **Research** is also by definition **Human Subjects**. In this case you will be asked to return to the **General Information Page** and select a different **Protocol Type**.
 - ii. If not asked to select a different Protocol Type, you will move to Step d.
- d. **Human Subjects Determination:** The questions in this section are designed to evaluate if your project meets the regulatory definition of “Human Subjects.” Answer all questions.
 - i. Under some circumstances, an activity that is **Human Subjects** is also by definition **Research**. In this case you will be asked to return to the **General Information Page** and select a different **Protocol Type**.
 - ii. If not asked to select a different Protocol Type, you will move to the next section, **Supporting Documents**.

An overview of Steps b-d is provided in this [flowchart](#).

IV. SUPPORTING DOCUMENTS

A. Relevant Documents

Depending on your responses, you may be required to submit one or more supporting documents in the smartform. Examples include:

- a. [Certification of Research on Decedent Information](#)
- b. [Request for Review of Protected Health Information Preparatory to Research](#)
- c. [Data Use Agreement](#)

- B.** Although you may be prompted to add an attachment(s) as you provide responses to questions within the smart form, a supporting documents section will appear at the bottom of the page for you to attach any study documents not previously attached. There are no specific document requirements for NHSR research; however, if you need to upload one or more documents

associated with this submission, you can do so in the Supporting Documents Section following the instructions below.

C. Instructions

- a. Click the "+Add Line" button to the right to upload a Supporting Document.
- b. In the dialogue box, Drag and Drop a file or Click "+ Choose" and browse for a file:
 - i. If browsing, locate the file and click open to attach. Note: all commonly used file types should be compatible except for ".msg" (Outlook messages).
- c. Enter a Name that will help you identify the document
- d. Select an Attachment Type from the drop-down list.
- e. Repeat Steps a-d as many times as necessary to add all necessary documents.

V. SUBMISSION INSTRUCTIONS

A. When the NHSR application is complete and ready for submission, submission instructions will appear. **The protocol may only be submitted by the PI.**

- a. **If you are not the PI** of the NHSR protocol, click "Notify PI to Submit" button to alert the PI that the protocol is ready for review and submission.
- b. **If you are the PI - either the original submitter or notified that the protocol is ready for submission** - you will be asked to confirm the completion and accuracy of the submission in the PI Certification and Submission section. If you do not agree with the assurance statement, you can permanently terminate the submission by clicking the "abandon" button.
- c. **Only after the PI has agreed with the statement of assurance can the protocol be submitted to the IRB for review.**

B. When the application is ready for submission

- a. Click "**Submit**" for it to be sent to the HRPP office.
- b. If required fields have no entry, error messages will appear
 - i. Complete all required fields and click "**Submit**" again.
- c. Submission's status will change from "In Progress" to "Submitted for Review"

VI. CHECKING THE STATUS OF A NHSR PROTOCOL

Click on "Manage Protocols" to view the submission type and status of NHSR Protocol

A. Submission Type Definitions:

- a. **New:** an initial (new) protocol submission and will remain listed as "New" post NHSR determination).
- b. **Close Request:** N/A for NHSR protocols. Although this button is available, do not select after the protocol is determined "NHSR" as it is not necessary.

B. Status Type Definitions:

- a. **In Progress:** This is the first version of the Protocol and it has not yet been submitted for review.
- b. **Submitted for Review:** This submission has been submitted to the compliance office for review for the first time.

- c. **Revisions in Progress:** This is the new version of a protocol created when the Revisions Requested action is taken. This version is sent to the researcher so they can make their changes.
- d. **Resubmitted:** This protocol submission has been returned by the compliance office and resubmitted by the researcher.
- e. **Not Human Subjects Research:** This protocol was identified by the IRB admin as Not Human Subject Research.
 - a. **Abandoned:** This submission was abandoned by the researcher.

VII. POST DETERMINATION REQUIREMENTS

Actions Post Determination: N/A

After a “NHSR” determination is issued for a study, no additional actions are needed. If changes are made to the study activities that may change this decision, a new protocol will need to be submitted in KR.