KUALI QUICK GUIDE
RELIANCE REQUEST

I. GENERAL INSTRUCTIONS

A. Protocol: For purposes of this guide and the Kuali Research (KR) system, "protocol" refers to an application submitted through the KR system.

B. This Quick Guide applies to: Preparation of a new protocol to request reliance on an external IRB for a multi-center study. It is not applicable for multi-center studies in which the LSUHSC IRB will serve as the Lead or Reviewing IRB.

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 Reliance Questionnaire Page.

b. The protocol adapts using built-in logic (smart-form) and the presentation of some questions or information is contingent on your prior responses.

c. **Submission: Only the PI can submit the protocol**; detailed information and instructions are provided in Section V and VI below.

D. Help Text: For some questions, additional information or instructions (*Help text*) are provided to assist you in answering the question. *Help text* may be present as additional text following the question or accessed by hovering over the **(?)** icon.

E. Attachments: Protocols and consent/assent/information sheet documents should initially be provide as Word documents; all other documents should be in PDF format.

F. New Protocol Overview: Reference this quick guide found on our Kuali Quickguide webpage for an overview and additional guidance related to each section as well as detailed submission instructions.

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. **Legacy Study:** Select "No"
f. **Press "Next"**

B. Level of Review:

a. **Select the "Protocol Type"** from the drop down menu: **Reliance Request**
b. **Press "Next"**

C. Performance Site(s):

a. Follow instructions to add all organizations (sites) where any research activity will occur or whose facilities and resources will be used to conduct the research.
b. If the site is not listed in the drop-down menu, select "Other" and provide the name of the facility.

D. Study Population

a. Select all population types involved in the study.
b. In the count field, enter the total number of participants, identifiable information, or identifiable biospecimens you will "enroll" in this study.

E. Research Personnel

a. The PI's name will automatically be listed in the top table
b. Follow instructions to list all personnel engaged in the research as well as any "Site Administrators" that need to access/edit the KR protocol or receive notifications.

F. Type of Research

a. Indicate the "Type of Research" being conducted. Based on your response, additional descriptive options for your to select will appear.
   i. Biomedical/Clinical
   ii. Social/Behavioral/Educational
   iii. Other

Once all required information has been entered on the General Information Page, press "Next" to begin the Reliance specific questionnaire.

III. PROTOCOL TYPE QUESTIONNAIRE PAGE

A. Questionnaire: Reliance Request

a. Select the proposed Reviewing IRB.
   i. LSUHSC-NO has master service (Reliance) agreements in place with the named IRBs (NCI CIRB, PETAL, Advarra & WIRB). Additional information about the IRB will not be required.
   ii. If you select "Academic Institution" or "Other," you will have to provide additional information about the proposed IRB including the reliance agreement. Reliance cannot be agreed to without an executed Reliance Agreement. A global reliance agreement is in place for studies using either the SMART IRB or IREx platforms.

b. If the proposed Reviewing IRB is a commercial IRB, answer the questions in the *Commercial IRB Eligibility* section to determine if the study is eligible for review by a commercial IRB.
c. If the proposed Reviewing IRB is not a named IRB, provide information about the IRB in the *Reviewing IRB Information* section.
d. Answer the remaining questions that address various aspects of the research study under consideration.
    i. If the study involves local collection of biospecimens, use of biohazards, or use of recombinant or synthetic DNA/RNA IBC approval will be required before the study may be implemented. You will be asked to provide the current status of the IBC application.

IV. SUPPORTING DOCUMENTS

A. Relevant Documents

Documents commonly required for a complete submission are listed below. Some of these documents may not be necessary for your particular submission. Follow the instructions on the form to determine which documents are required.

a. Protocol
b. Consent form or documentation of waiver from the Reviewing IRB
c. LSUHSC ICF cover letter
d. HIPAA authorization form or documentation of waiver from the Reviewing IRB
e. Reliance Agreement
f. Any other documents from the Reviewing IRB

B. 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. PROTOCOL SUBMISSION

A. PI IDENTIFICATION

The protocol may only be submitted by the PI.

a. Select if you, the person completing or currently viewing the form, are or are not the PI
    i. **If you are not the PI**, select the "Notify PI to Submit" to notify PI that protocol is ready for submission.
    ii. **If you are the PI (either the original submitter or notified that the protocol is ready for submission),** you will be asked to provide your statement of

assurance. If you do not agree with the statement, you can permanently terminate the submission by clicking the "abandon" button.

iii. *Reference the New Protocol Overview Quick Guide for Detailed Guidance*.

VI. PI CERTIFICATION AND SUBMISSION

Only after the PI has agreed with the statement of assurance should the protocol be submitted to the IRB for review.

A. When the protocol 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"

VII. DEPARTMENT CERTIFICATION

Once the protocol is submitted for review, the HRPP office will assign the Department Head as an ancillary reviewer. The Protocol will not be "approved" until the ancillary review has been approved by the Department Head (*i.e.*, Department certification provided).

VIII. CHECKING THE STATUS OF PROTOCOL SUBMISSIONS

Click on "Manage Protocols" to view the submission type and status of all your protocols

A. Submission Type Definitions:

a. **New:** an initial (new) protocol submission.
b. **Initial:** "New" submission that is approved by the IRB (this does not include NHSR protocols which will remain listed as "New" post NHSR determination).
c. **Amendment:** submission to request modification of an approved protocol.
d. **Renewal:** submission to request renewal/re-approval of a protocol.
e. **Renewed:** "Renewal" submission that is approved by the IRB.
f. **Close Request:** submission to request closure of an approved protocol.

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 IRB 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 IRB Office and resubmitted by the researcher.
e. **Approved:** This version of the protocol has been approved by the IRB Office.
f. **Disapproved:** This protocol was disapproved by the compliance office.

g. **Amendment in Progress:** An Amendment is being worked on in this version and has not yet been submitted for review.
h. **Renewal in Progress:** A Renewal is being worked on and has not yet been submitted for review.
i. **Close Request in Progress:** A request to close the protocol is being worked on and has not yet been submitted for review.
j. **Returned to Researcher:** The Protocol has been Returned to the PI for general revisions.
k. **Suspended:** This protocol has been suspended and is not currently active.
l. **Expired:** This protocol is expired and is no longer active.
m. **Exempt:** This protocol was approved as Exempt.
n. **Closed:** This protocol has been closed and is no longer active.
o. **Abandoned:** This submission was abandoned by the researcher.
p. **Not Human Subjects Research:** This protocol was identified by the IRB admin as Not Human Subject Research.
q. **External Reliance:** This protocol is part of a Single IRB Protocol being managed by another institution.