KUALI QUICK GUIDE

OVERVIEW OF NEW PROTOCOL SUBMISSION

I. GENERAL PROTOCOL INSTRUCTIONS

A. Protocol: For purposes of this guide and the Kuali Research (KR) platform, "protocol" refers to an application submitted through the KR system. As a principal investigator (PI) or regulatory coordinator acting on behalf of a PI, you can prepare and manage your protocols throughout their life cycle to ensure compliance with regulations and policies when human and/or animal subjects are involved in research.

B. This Quick Guide applies to: Creation of New Protocol Submissions.

C. Navigation:

a. Upon logging into KR, simply click the 'New Protocol' button in the top right-hand corner of the Manage Protocols screen to begin.

b. In order to move through the smart form, you must complete all sections within the General Information Page, starting with the Study Identification and Protocol Type sections. Once you have completed these sections, press "**Next**" to continue completing the General Information Page.

c. Once you have completed the General Information Page sections, press "**Next**" to complete the protocol type specific Questionnaire Page **N/A for NHSR submissions**

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

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

f. **"Resubmit" button:** Regardless if the user is or is not the PI, if the user has "full access" as designated in the Research Personnel Table, the "Resubmit" button will be active if the protocol is returned to the study team.

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 placing the mouse pointer on *Help* icon, ?.

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

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 KR.

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 KR.
   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. Protocol Type:

a. **Select the "Protocol Type"** from the drop down menu which includes the following seven options:
   i. Not Human Subject Research*
   ii. Reliance Request
   iii. Exempt Research
   iv. Expedited
   v. Full Board
   vi. Humanitarian Use Device Request (HUD)**
   vii. Emergency Use of a Test Article (EUTA)**
b. **Press "Next"**

If the protocol type selected is "Not Human Subject Research," **Sections III C-G below will not appear; the user will be immediately directed to complete the NHSR questionnaire section and, if the criteria is met, instructions will appear for submission.*
***If the protocol type is EUTA or HUD, some sections will not appear or will be modified to capture necessary information. The process for notifying the PI to submit the protocol should always be followed when the user completing the submission is not the PI.*

C. Funding and Sponsor Information Table:

a. Click the '+Add Line' button to access the table dialogue box.
b. Select a funding source (type) applicable to the study and provide all requested details based on your selection (e.g., industry sponsor details).
c. Repeat Steps a & b to list additional funding types as needed.
d. *N/A for EUTA and HUD*

D. Performance Site(s):

a. Follow instructions to add all organizations (sites) that are engaged in the research, (*i.e.*, any organization where subject records will be accessed, or where research related interactions and/or interventions occur.)
b. If the study will be held outside of LSU Health, you will be required to attach a letter, email, or other correspondence indicating agreement to conduct research at the external facility.
   i. *Performance site letter of permission: N/A for HUD and EUTA*.

c. If the site is not listed in the drop-down menu, select "Other" and provide the name of the site.

E. Study Population

a. As applicable, indicate the type of participants that may be included, such as adults, children (subjects under the age of 18) or students.
b. Based on the protocol type and participant type(s) selected, vulnerable population criteria and additional questions may appear.
c. Enter the total number of subjects to be enrolled in the research.
d. *N/A for EUTA*

F. Research Personnel

a. The PI's name will automatically be listed in the table.
b. Use the pencil icon to edit the PI information, completing all the required fields, such as the affiliation and level of KR protocol access (see below).
c. Click '+Add Line' to list additional research personnel, typing the individual's **Name**. If the person is a user in the KR system, the individual will automatically appear for you to select. Upon selection, the email will automatically populate. Next, enter the rest of the required fields:
    i. Affiliation (HSC or NON-HSC)
    ii. Protocol Role
    iii. Level of protocol access
d. Training information will appear for the IRB staff to review during training verification.
e. Attachments Table:
    i. HSC Researchers:
        1. CITI training certificates completed through a different institution (not LSUHSC)
    ii. Non-HSC Researchers:
        1. Certificates of completion of all required training described here.
        2. Curriculum Vitae (CV) for all Sub-Investigators
        3. Documentation of Approval Letters or Necessary Agreements as applicable
    iii. **HUD: Do NOT attach any research training documents. Research training certification is not required if the HUD will be used in clinical practice and not in a clinical investigation (i.e., research). CVs of other physicians (i.e., Sub-Investigators) is also not required.
f. **Individual Not a User in KR:**
    i. **Answer "Yes" to this Question**: Are you unable to find one or more individuals when typing their name in the Research Personnel Table above?
    ii. Follow the instructions that appear in the protocol and reference the "Accesing Kuali" quick guide for specific details.

iii. If you wish, you may complete and submit this protocol without including the individual(s) on the study team. You will then have to request an amendment to the approved protocol to add the individual(s).

iv. Alternatively, you may complete but not submit the protocol until after the individual(s) have notified you of their registration as"users" in KR. At that time you can add them to the Research Personnel Table and submit the protocol.

g. *N/A EUTA*

G. 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

b. *N/A for EUTA or HUD*

Once all required information has been entered on the General Information Page, press "Next" to begin the Protocol-Type Specific questionnaire.

III. PROTOCOL TYPE QUESTIONNAIRE PAGE

A. Questionnaire: Protocol Type

a. The Questionnaire that appears is directly linked to the Protocol Type selected.

b. If any of your responses indicate that your project is not eligible for review as the protocol type selected, you will be alerted to revise your response to the "protocol type" selection.

c. *See the protocol-type specific quick guides for additional details.*

IV. SUPPORTING DOCUMENTS/ATTACHMENTS SECTION

A. Relevant Documents

Although you may be prompted to add attachments as you provide responses to questions within the smart form, an attachment section will appear at the bottom of the Questionnaire for you to attach any study documents not previously attached but required based on your research activities. Document requirements vary based on protocol types; however, you will be alerted of these supporting document requirements based on your Questionnaire responses and by consulting the protocol specific guides.

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. PI CERTIFICATION

A. PI Identification

The protocol can only be submitted by the PI.

a. Select if you, the person completing or currently view 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.

1. You will be prompted with a message if you are sure you wish to notify the PI of protocol. NOTE: Error messages will not appear if required fields are missing and the PI will have to fill in the missing information before being able to submit. Therefore, make sure to check the protocol for accuracy and completion prior to selecting the "Notify PI to submit" button.
2. Once you confirm that you are ready for the PI to be notified, the PI will be sent a system generated notification with a link to the protocol to review and provide his/her applicable certifications.
3. Once the protocol is opened by the PI, the PI should click on the *Submission* button on the left panel menu and then the *PI Certification & Submission* button. The PI should respond to the statement of assurance and take the appropriate action as indicated in the protocol (submit or abandon).

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.

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

B. ***Modified Version of certification for EUTA, NHSR, and Post-Approval Submissions (except Changes in PI).*** *The PI will still have to agree to the completion and accuracy of the protocol submission prior to submission to IRB.*

VI. SUBMISSION INSTRUCTIONS

A. 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"

VII. DEPARTMENT CERTIFICATION

A. Once the protocol is submitted for review, the HRPP office will assign the PIs one-over (e.g., Department Head, Center Director, Dean of School) as an ancillary reviewer.

a. The IRB will not provide final approval of the Protocol until the one-over has provided his/her certification.
b. *N/A for EUTA or NHSR*

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