KUALI QUICK GUIDE

OVERVIEW OF NEW PROTOCOL SUBMISSION

I. GENERAL PROTOCOL INSTRUCTIONS

A. Protocol: For purposes of this guide and the Kuali Research (KR) Protocols module, "protocol" refers to an application submitted through the KR system. As a principal investigator (PI) or full access individual 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. Auto-save logic is built into KR and a "Save complete" alert will display at the bottom the page when 1) the preliminary protocol information is completed and 2) additional information is added and edited throughout the protocol. Therefore, there is no save button in the system.

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

a. To move through the smart form, you must first complete the Study Identification and Protocol Type sections of the General Information Page. The Action button of 'Next' guides you through the completion of the preliminary protocol information required before it can be saved. After the initial save, you'll be taken to view the entire protocol.
b. Complete the remainder of the General Information Page sections.
c. Once the information is complete, navigate to additional pages associated with the selected Protocol Type (*N/A for NHSR submissions*):
d. **Additional Page Navigation**:
   i. Press " **Next** " at the bottom of the page to view and complete additional pages (e.g., Protocol Type Questionnaires and Submission) - OR -
   ii. Use left-hand side of the screen to easily navigate to the desired sections and pages in the protocol. This is quick navigation is especially useful since the protocol has numerous sections with large amounts of information within them.
e. The protocol adapts using built-in logic (smart form) and the presentation of some questions or information is contingent on your prior responses.

E. Level of Access:

a. Those initiating protocols are automatically granted "Full Access" permission.
b. Research personnel are added to the Protocol form where they are assigned the appropriate level of access. Their level of access can only be modified in the Protocol Personnel Table. See Section II (F) for details.
c. Note: Only full access individuals can take the "submit" action.

F. Submission: Individuals that initiate the protocol or have "full access" permission as designated in the Protocol Personnel Table can take "Submit" and "Resubmit" actions; detailed information and instructions are provided in Sections IV & V below.

G. 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, **?**.

H. Attachments: Unless otherwise directed in the application, study documents requiring HRPP/IRB review and approval should be listed in the main supporting documents section of the application. Only attachments uploaded in this section will be listed on the approval letter with Document Type, File Name, and Description all appearing. Attachments uploaded in other areas of the application, known as "in-line attachments," will not be listed in the approval letter but are required for the submission when prompted. Consent/assent/information sheets should initially be attached as word documents and final versions provided as PDFs; all other documents should be in PDF format. Approval watermarks will only appear on PDF file types.

II. GENERAL INFORMATION PAGE

A. Study Identification:

a. **Title:** Enter the title of your study.

b. **Principal Investigator:**

- Begin typing the first or last name of the PI and Kuali users will begin to appear
- Click the PI's name and it will be entered in the field.

c. **Department:** Primary appointment of PI

i. This field will automatically populate for PI's that have their department associated with their user profile in the system. If the information is correct, no action is needed.

- If the field is blank or incorrect, begin typing the name of the department and options will automatically appear from the list of departments stored in Kuali.
  - Click the correct department 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. **Anticipated Start** and **Estimated End Dates:** Enter the applicable start and approximate end dates of the study.

f. **National Clinical Trial (NCT) number (if applicable):** enter value as applicable.

g. **Press "Next"**

B. Protocol Type:

a. **Select the "Protocol Type"** from the drop down menu which includes the following seven options:

- Not Human Subject Research*
- Reliance Request
- Exempt Research
- Expedited
- Full Board
- Humanitarian Use Device Request (HUD)**

- Expanded Access to a Test Article (EATA)**

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, submission instructions will appear.*
***If the protocol type is EATA or HUD, some sections will not appear or will be modified to capture necessary information.*

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. 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 may be required to attach a letter, email, or other correspondence indicating agreement to conduct research at the external facility.
    - *Performance site letter of permission: N/A for HUD and EATA*.
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 EATA*

F. Protocol Personnel – Those initiating protocols are automatically granted "Full Access" permission without being added to Protocol form. If their activities go beyond submitting/initiating protocols and are considered "research personnel," they need to add themselves to the Protocol Personnel table.

a. The PI's name will automatically be listed the Protocol Personnel Table.
b. Use the pencil icon to edit the PI information, completing all the required fields, such as the affiliation type (see all required fields listed 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:

- Protocol Role
- Level of Protocol Access:
    1. Full Access: Gives the user ability to view/edit the entire protocol and take actions like submit, initiate an Amendment, Renewal, etc.
    2. Read-Only: Gives the user ability to view the entire protocol and any attachments but can make no updates or take actions on the protocol.
- Affiliation (HSC or Non-HSC):
  If Non-HSC, you will be required to respond to the "IRB of Record" question:
    a. Their Home Institution
    b. LSUHSC IRB
    c. N/A if Protocol Type is NHSR, HUD, or EATA

d. Training that is available in system will display but will not prevent protocol submission.

e. Attachments – HSC Researcher:
- Option to upload CITI training certificates completed through a different institution (not LSUHSC)

f. Attachments – Non-HSC Researcher:
- LSUHSC-NO (HSC) Serving as the IRB of Record for Non-HSC Personnel – Attachments Guidance and Non-HSC Researcher Documents Table Displays
- Non-HSC's Home Institution Serving as their IRB of Record – Attachments Guidance and Non-HSC Researcher Documents Table Displays
  ***HUD/EATA/NHSR: Disregard all mention of training requirements.*

g. **Individual Not a User in KR:**
- **Answer "No" to this Question**: Were you able to add all individuals involved in the study to the Protocol Personnel Table above?
- Follow the instructions that appear in the protocol and reference the "Accessing Kuali" Quick Guide for specific details.
- 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).
- 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 Protocol Personnel Table and submit the protocol.

h. *N/A EATA and NHSR*

G. Type of Research

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

- Other

b. *N/A for EATA or HUD*

H. Reliance Arrangement:

a. Indicate if this is a multi-center, single IRB study AND are you requesting the LSUHSC-NO IRB to serve as the Reviewing (Lead) IRB.

b. If you click "Yes," the Participating Sites option will appear at the top of the protocol option menu bar. Click on the Participating Sites bar, then click "+Participating Site" to add the relying site information. Do not move forward with the next step until all sites relying on HSC for the review of this study are listed in this area.

Once all required information has been entered on the General Information Page, press "Next" to begin the next page (*Protocol Reference or Protocol-Type Specific Questionnaire)*

II. PROTOCOL REFERENCE PAGE

This page displays for exempt research, expedited, and full board protocol types. When completing the fields on this page, only reference the location(s), including page numbers, within the Protocol Document where this information is provided (e.g., 2.1 Rationale, pp. 5-6).

A. Background - *Typically includes a summary of relevant literature and/or prior experience leading to the formulation of this study*.

B. Rationale/Significance - *Typically includes purpose of study, problem statement, potential risks and benefits, potential impact*

C. Research Purpose/Objectives - *Typically includes the hypothesis, reason for the study, research question(s), and primary & secondary objectives in terms understandable to a layperson or non-scientist*.

D. Study Design - *Typically includes general design description, study population, eligibility criteria, outcome variables, etc.*

E. Study Methods - *Typically includes the description of all study interventions, procedures, assessments, statistical methods, data handling and record keeping, etc.*

Once all required information has been entered on the Protocol Reference Page (if applicable), 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 and Protocol Type Guidance for details.*

B. Supporting Documents Section

Only attachments uploaded in this section will be listed on the approval letter with Document Type, File Name, and Description all appearing. Document requirements vary based on protocol types; however, you will be alerted of these supporting document requirements based on your Questionnaire responses.

Instructions:

a. Click the "+Add Line" button to the right to upload a Supporting Document.
b. Select a Document Type from the drop-down list.
c. Select "Clean" as the edit type. "Tracked-changes" edit types are ONLY for amendment submissions.
d. Enter a Name that will help you identify the document. Please note this information will appear in the final approval letter.
e. 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).
f. Add any additional comments regarding the attachment (if applicable).
g. Repeat Steps a-f as many times as necessary to add all necessary documents.

Once all required information and attachments have been entered on the Protocol-Type Specific Questionnaire Page, press "Next" to begin the Protocol Submission.

IV. PROTOCOL SUBMISSION PAGE

The Protocol may be submitted by an individual with full access protocol permission.

A. Conditions: Whether the submitter is the PI or an individual submitting on behalf of the PI, the PI is ultimately responsible for what is submitted as part of this application to the IRB and the conduct of the study once it is approved by the IRB.

B. Certification and Submission:

a. Review all applicable certifications.
b. Respond to the statement and take the appropriate action as indicated in the protocol (submit or abandon).
    i. **Abandon:** If you do not agree with the statement, you can permanently terminate the submission by clicking the "abandon" button.
    ii. **Submit:** Only after agreeing with the statement of assurance should the protocol be submitted to the HRPP/IRB for review.

C. ***Note:*** *There are modified certifications for EATA, NHSR, and Post-Approval Submissions (except Changes in PI). The submitter will still have to agree to the completion and accuracy of the protocol prior to IRB submission.*

V. SUBMISSION INSTRUCTIONS

A. Once you have completed all sections of the Protocol, uploaded all required documents, and agreed to the statement of assurance:

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. DEPARTMENT CERTIFICATION AND ANCILLARY REVIEWERS

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.

B. **Additional ancillary reviewers may be assigned based on performance site (Non-HSC Site Review), study activities (e.g., IBC requirements), and financial conflicts of interest (COI).**

a. IRB/HRPP will not provide final study approval until all applicable ancillary reviews have been approved.
b. *N/A for EATA or NHSR*

VII. 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.