# KUALI QUICK GUIDE

# EXPEDITED AND FULL BOARD

## I. GENERAL INSTRUCTIONS

**A. This Quick Guide applies to:** Creation of New "Expedited" or "Full Board" Protocols

**B. 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 Protocol Reference Page, where you only reference the location within the attached Protocol Document where the requested information is found. Once the Protocol Reference Page is complete, press "**Next**" to continue with the Expedited or Full board Research Questionnaire Page.

**C. Website Guidance:** Initial review of non-exempt, human subjects research may be conducted by the Full Board at a convened meeting or by the Expedited review procedure. The latter is applicable to minimal risk studies in which research activity is limited to one or more of federally-defined Expedited Review Categories 1-7; it is conducted by the IRB Chair or an experienced IRB member designated by the Chair. More information is available at the IRB website.

**D. 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.

a. **NOTE:** A study protocol, "Protocol Document," is required attachment and can be created using Protocol Builder or any template that includes the required elements as listed in the Protocol Reference Section of the application.

**E. New Protocol Overview**: Reference this quick guide found on our Kuali Quickguide webpage for a new submission 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 Kuali users will begin to appear

ii. 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.
ii. 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.
    1. 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: "**Expedited" or "Full Board"**
b. **Press "Next"**

**C. Funding and Sponsor Information Table:**

a. Select the Funding Type(s) for the study and provide all requested details based on your selection (e.g., industry sponsor details). *Reference the New Protocol Overview Quick Guide for specific instructions.*

**D. Performance Site(s):**

a. Follow instructions to select all organizations (sites) where LSUHSC-NO (HSC) investigators 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 activities will be held outside of HSC, you may be required to attach a letter, email, or other correspondence indicating agreement to conduct research at the external facility.

**E. Study Population**

a. As applicable, indicate the type of participants that may be included in the study, such as children (subjects under the age of 18), subjects lacking consent capacity, prisoners, and students.
b. **Vulnerable Populations -** based on your response, additional questions will appear in this section and in the protocol type specific page as applicable.
    **i.** For more information about vulnerable populations in human subjects research, please review the HSC-HRPP Policies (7.00: Human Subject Participation)
c. In the count field, enter the total number of subjects to be enrolled in the research.

**F. Research Personnel**

a. The PI's name will automatically be listed in the Protocol Personnel Table.
b. Follow instructions in the protocol to list all research personnel.
c. *Reference the New Protocol Overview Quick Guide for specific instructions on adding personnel to the table.*
a. **Individual Not a User in KR:** *Reference the Accessing Kuali Quick Guide.*

**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.

**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 Protocol Reference Page.**

## III. PROTOCOL REFERENCE PAGE

**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 Protocol Reference Page, press "Next" to begin the Expedited or Full Board Research specific questionnaire.**

## IV. PROTOCOL TYPE QUESTIONNAIRE PAGE

**A. Questionnaire: Expedited or Full Board Research**

a. The purpose of the first question is to determine if the research is greater than minimal risk. Your response should match the Protocol Type selected on the first page. If you have conflicting responses (e.g., Protocol Type is Expedited and you indicate that the study is greater than minimal risk, update the Protocol Type to Full Board).

i. The protocol adapts using built-in logic (smart-form) based on your responses to some questions. You be alerted with "Protocol Type checks" throughout the application, prompting you to confirm if the protocol type criteria is met.

ii. If your response indicates that your project does not qualify for the Protocol Type selected, you will be alerted to update your responses and revise the Protocol Type on the first page.

b. Both the Expedited and Full Board questionnaire contain the same sub-sections.
c. Complete all general expedited and full board questions and sections.
d. Additional questions will appear based on information from the General Information Page (vulnerable subjects selected), as well as other previous answers and the risk assessment results.
e. Expedited Studies: Select ALL categories that apply to the proposed expedited study and answer all questions that appear.
f. Full Board Studies: Full Board Studies are considered greater than minimal risk and are expected to provide a more robust data safety monitoring plan in the applicable section.
g. Notable Sections include:
   i. Informed Consent Process: Additional questions will appear based on information from the General Information Page - Subject Population Section (vulnerable subjects selected), as well as other previous answers.
      1. This section should describe how (if any) informed consent will be sought from subjects after they have been recruited for the study.
      2. Waiver Guidance: click here
   ii. Child Assent & Parental Consent Process: Will appear for either type of study which chooses Children as a subject population.
   iii. HIPAA: The HIPAA section will appear for Expedited and Full Board questionnaires and will direct users to upload HIPAA forms or complete the Waiver Questionnaire based on their responses.

## V. ATTACHMENTS

### A. Relevant Documents

**Expedited and Full Board studies are required to upload a protocol document.** Additional required documents are dependent on the study activities being conducted, and you will be alerted of these supporting document requirements based on your questionnaire responses.

### B. Required Attachment for Expedited Studies:

a. Protocol Document
b. Informed consent document or study information sheet (unless a waiver has been requested in the informed consent questionnaire)
c. HIPAA authorization (if HIPAA applies and a waiver has not been requested in the HIPAA questionnaire)
d. Assent (if children capable of assent are being enrolled and a waiver has not been requested in the assent and parental consent questionnaire)
e. All recruitment materials (advertisements, flyers, phone scripts, etc.)
f. All data collection instruments (surveys, questionnaires)

**C. Required Attachment for Full Board Studies**:

a. Protocol Document
b. Informed consent document or study information sheet (unless a waiver has been requested in the informed consent questionnaire)
c. HIPAA authorization (if HIPAA applies and a waiver has not been requested in the HIPAA questionnaire)
d. Assent (if children capable of assent are being enrolled and a waiver has not been requested in the assent and parental consent questionnaire)
e. All recruitment materials (advertisements, flyers, phone scripts, etc.)
f. All data collection instruments (surveys, questionnaires)
g. All Drug or Biological Product documentation, if applicable (e.g., Investigator's Drug Brochure, package inserts, IND Approval, or documentation of IND Exemption, etc.)
h. All Medical Device documentation, if applicable (e.g., Investigator's Device Brochure; IDE Approval; documentation of IDE exemption; or documentation from the sponsor with an explanation of NSR determination, etc.)

**D. 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.

## VI. PI CERTIFICATION & SUBMISSION

**A. PI IDENTIFICATION**

a. **The protocol may only be submitted by the PI.**
a. If you are the PI, 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. *Reference the New Protocol Overview Quick Guide for Detailed Guidance*.

## VII. SUBMISSION INSTRUCTIONS

**A. When the Expedited/Full Board Research 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"

## VIII. DEPARTMENT CERTIFICATION AND ANCILLARY REVIEWS

**Once the protocol is submitted for review, the HRPP office will assign the Department Head as an ancillary reviewer.** Additional ancillary reviewers may be assigned based on the performance sites and study activities. The study will not be approved until all applicable ancillary reviews have been approved.

## IX. CHECKING THE STATUS OF AN EXPEDITED/FULL BOARD PROTOCOL

Click on "Manage Protocols" to view the submission type and status of your expedited/full board protocol. Once your Expedited/Full Board Protocol is Approved, the status will be:

**A. Expedited/Full Board Status Post Approval:**

a. **Submission Type:** Initial
b. **Review Type:** Expedited or Full Board
c. **Status:** Approved
d. **Continuing Review Date for Expedited:** 3 Years from date of expedited approval date determination date for non-FDA regulated studies.
e. **Continuing Review date for Full Board or FDA regulated Expedited Studies:** 1 year from approval date.

**B. Submission Type Definitions**:

a. **New:** an initial (new) protocol submission.
b. **Initial:** "New" submission that is approved by the IRB
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.

**C. 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. **Approved:** This version of the protocol has been approved by the compliance office.
e. **Disapproved:** This protocol was disapproved by the compliance office.
f. **{Submission Type: Amendment} In Progress:** An Amendment is being worked on in this version and has not yet been submitted for review.
g. **{Submission Type: Renewal} In Progress:** A Renewal is being worked on and has not yet been submitted for review.

h. **{Submission Type: Close Request} In Progress:** A request to close the protocol is being worked on and has not yet been submitted for review.
i. **Closed:** This protocol has been closed and is no longer active.
j. **Abandoned:** This submission was abandoned by the researcher.

## X. POST APPROVAL REQUIREMENTS

**A. RENEWAL:**

a. **EXPEDITED**
   i. **For non FDA-regulated expedited studies, investigators must submit a Status Update every three years.** Status Updates are submitted using the *Renewal* form in KR via the "Renew" button.
   ii. FDA regulated expedited studies must be submitted annually for renewal as they are not exempt from continuing review requirements.

b. **FULL BOARD:**
   i. **Renewals must be submitted annually by the PI.** Submit the *Renewal* form in KR via the "Renew" button.

**B. REPORTABLE NEW INFORMATION** Events and non-compliance that meet the regulatory criteria for an Unanticipated Problem (UP) must be reported promptly to the IRB (within 3-5 days of becoming aware of an event). Similarly, updated study information or other information that identifies a deficiency, recommends a change in the research procedures, potentially alters the risk/benefit analysis or impacts on the safety and welfare of participants, also must be reported promptly to the IRB. Submit RNIs via the "Report an Event" button in KR

C. **AMENDMENTS** should be submitted and approved by the IRB before the study team implements any modifications to previously approved research. Submit an amendment in KR via the "Amend" button.

**D. CLOSURE** should be submitted if all research-related interventions or interactions with participants have been completed and collection and analysis of identifiable private data (as described in the IRB-approved protocol) are finished. Close the study via the "Close Request" action in KR.