KUALI QUICK GUIDE
EXPEDITED AND FULL BOARD

I. GENERAL INSTRUCTIONS

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

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 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. Attachment: Protocols and consent/assent/information sheet documents should initially be provided as Word documents; all other documents should be in PDF format. A Full Board study is required to provide and upload a protocol document, an expedited study is not required to provide a protocol. Additional documents that are necessary to upload will be dependent on the study activities being conducted, and you will be alerted of these supporting document requirements based on your questionnaire responses.

A. 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. 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) 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.

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 including vulnerable populations in human subjects research, please be sure to review the HSC-HRPP Policies.

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 Research Personnel Table.

b. Follow instructions in the protocol to list all research personnel, including "Site Administrators" that need to edit the KR Protocol or receive notifications.

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 your to select will appear.

Once all required information has been entered on the General Information Page, press "Next" to begin the Expedited or Full Board Research specific questionnaire.

III. 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.

i. The protocol adapts using built-in logic (smart-form) based on your responses to some questions. If your response indicates that your project does not qualify for expedited or full board review, you will be instructed to revise your response to the protocol type question on the first page. However, if your protocol qualifies for expedited or full board review, no revision of protocol type on the first page is required regardless of what your responses reveal.

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.

IV. ATTACHMENTS

A. Relevant Documents

A Full Board study is required to provide and upload a protocol document, an expedited study is not required to provide a protocol. Additional documents that are necessary to upload will be 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. Informed consent statement or study information sheet (unless a waiver has been requested in the informed consent questionnaire)
b. HIPAA authorization (if HIPAA applies and a waiver has not been requested in the HIPAA questionnaire)
c. Assent (if children capable of assent are being enrolled and a waiver has not been requested in the assent and parental consent questionnaire)

d. All recruitment materials (advertisements, flyers, phone scripts, etc.)
e. All data collection instruments (surveys, questionnaires)

C. Required Attachment for Full Board Studies:

a. A copy of the protocol
b. Informed consent statement 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)

D. 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. 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*.

VI. 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"

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 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.

IX. 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.