KUALI QUICK GUIDE
CLOSURE 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: submitting a Closure Request for an approved and active study to the IRB.

C. Navigation:

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

b. **Submission: Only the PI can submit the Closure Request;** detailed information and instructions are provided in Section III (H and I) below.

c. **Overview of New Protocol Submissions**: Reference this quick guide found on our Kuali Quickguide webpage for an overview and additional guidance related to each section of the approved protocol as well as detailed instructions on the submission process.

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 over the *Help* 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.

II. ACCESSING THE CLOSURE REQUEST FORM

A. Log in to Kuali Research, click *"Manage Protocols"* on the left panel, and select the approved and active protocol of interest from the list of all your protocols.

B. From the protocol page, click *"Request Close"* on the right-hand panel to access the **Closure Request Form**.

III. COMPLETING & SUBMITTING THE CLOSURE REQUEST FORM

A. Study Type & Status

a. This section of the form asks preliminary questions to identify the type of study under consideration.

i. If a Reliance study, the study cannot be closed with the LSUHSC IRB until it has been approved for closure by the IRB of Record and documentation of approval is available.

ii. If an industry-sponsored study, the study cannot be closed with the LSUHSC IRB until the sponsor has conducted the site closure visit or has provided a document confirming that the site closure visit will not occur.

b. Answer all questions. Based on your responses, the form will instruct you to:
    i. provide the approval letter from the IRB of Record and submit the Closure form;
    ii. abandon the form because the study is not eligible for closure at this time; or
    iii. continue to the next question to indicate the reason why the study is being closed .
c. Depending on the reason for the closure request, other sections will appear on the form as listed below.

B. Research Progress: Provide a brief summary of the study's progress, including any observations or findings, during the most recent approval period.

C. Research Participants: Provide basic statistics about study participants include number enrolled and withdrawn. If any have withdrawn, indicate the reason for withdrawal. Also, indicate if members of a vulnerable population have enrolled in the study.

D. Reportable New Information (RNI): The purpose of this section is to provide an opportunity for the investigator to report RNIs or events that have occurred during the most recent approval period but were not reported to the IRB.

a. If the RNI/Event in question required prompt reporting to the IRB, then complete and submit one or more Reportable Event Forms before the Closure Request can be submitted and reviewed.
b. If the RNI/Event in question did not require prompt reporting to the IRB, then report it here following the instructions provided.

E. Amendments: The purpose of this section is to provide an opportunity for the investigator to report any modifications that have occurred during the most recent approval period but were not reported to the IRB. If there were any such modifications, then complete and submit:

i. An **Amendment Form** describing the unreported modifications and, if applicable, make edits to the protocol that follows the Closure Request Form.
ii. A **Reportable Event Form** to document this instance of non-compliance.
iii. Submit the **Closure Request Form** after the amendment is approved and the non-compliance has been acknowledged by the IRB.

F. Clinical Trial Requirements: When meeting the definition of an *investigator-initiated clinical trial*, the principal investigator is responsible for ensuring additional requirements related to conduct of clinical trials are met. If the study being closed is an *investigator-initiated clinical trial*, you will be asked to:

a. indicate if the research has been registered, and results posted, at *ClinicalTrials.gov*,
b. indicate if a copy of the consent form has been posted to a federal website, or
c. provide justification for why these actions have not been carried out.

G. Supporting Documents

a. If applicable, attach any relevant documents not previously attached to the application.

H. Submission Instructions

The Closure Request can only be submitted by the PI.

a. **If you are not the PI**, select the "Notify PI to Submit" to notify PI that Closure Request is ready for review and submission.
b. **If you are the PI - either the original submitter or notified that the Closure Request is ready for submission -** you will be asked to confirm the completion and accuracy of the submission in the PI Certification and Submission section. If you do not agree with the assurance statement, you can permanently terminate the submission by clicking the "abandon" button.

I. PI Certification & Submission

a. **Only after the PI has agreed with the statement of assurance should the Closure Request be submitted to the IRB for review.**
b. **When the application is ready for submission:**
   i. Click "**Submit**" for it to be sent to the HRPP office.
   ii. If required fields have no entry, error messages will appear
   iii. Complete all required fields and click "**Submit**" again.
   iv. Submission's status will change from "In Progress" to "Submitted for Review"