KUALI QUICK GUIDE

RENEWAL

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 an annual **Continuing Review** or a triennial **Status Update** for an approved study.

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 Renewal;** detailed information and instructions are provided in Section III (I and J) 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 RENEWAL FORM

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

B. From the protocol page, click *Renew* on the right hand menu.

III. COMPLETING & SUBMITTING THE RENEWAL FORM

A. General Considerations

a. The **Renewal Form** is used to submit both an *annual* **Continuing Review** and the *triennial* **Status Update** for Exempt and qualified Expedited and Full Board studies.

b. Depending on your responses to certain questions, you may be required to submit a request for study modification (*Amendment*) as part of the *Renewal* process. The form will instruct you when an *Amendment* is necessary and also provide instructions for accessing the **Amendment Form**. Instructions for completing the **Amendment Form** are provided here.

c. The type and amount of information requested varies significantly depending on whether the submission is an annual **Continuing Review** or a triennial **Status Update.**

The built-in logic of the form will guide you through the process once you have made a selection.

B. Study Type & Status

a. This section of the form asks preliminary questions to identify the type of submission and type of study under consideration.
   i. If a triennial **Status Update**, the **Renewal Form** is abbreviated and many of the sections listed below are not displayed.
   ii. If a **Reliance** study, a limited number of questions are asked but you will need to provide a letter of approval from the IRB of Record in order to complete the Renewal submission.

b. Answer all questions and go to the next available section.

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

D. **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.

E. **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 Renewal 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.

F. **Study Modifications:** 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 Renewal Request Form.
ii. A **Reportable Event Form** to document this instance of non-compliance.
iii. Submit the **Renewal Request Form** together with the **Amendment Form** but after the non-compliance has been acknowledged by the IRB.

G. 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 renewed 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.

H. Supporting Documents

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

I. Submission Instructions

The Renewal can only be submitted by the PI.

a. **If you are not the PI**, select the "Notify PI to Submit" to notify PI that renewal is ready for review and submission.
b. **If you are the PI - either the original submitter or notified that the renewal 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.

J. PI Certification & Submission

a. **Only after the PI has agreed with the statement of assurance should the renewal application 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"