


KUALI QUICK GUIDE

AMENDMENTS

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 request for modification to an approved study for IRB review and approval.
- 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 Amendment;** detailed information and instructions are provided in Section III (F and G) below.
 - c. **Overview of New Protocol Submissions:** Reference this quick guide found on our [Kual Quickguide webpage](#) for an overview and additional guidance related to each section of the approved protocol as well as detailed information 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 AMENDMENT FORM

- A. Log in to Kuali Research, click *Protocols* 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 *Amend* on the right panel menu to access the **Amendment Form**.

III. COMPLETING & SUBMITTING THE AMENDMENT FORM

- A. **General Considerations**
 - a. Amending a protocol involves completing the **Amendment Form** and, under most circumstances, revising appropriate fields within the **approved Protocol** (i.e., application). Once the *Amend* button is clicked, both the Amendment Form and the approved Protocol will be displayed.
 - i. The **Amendment Form** will inform you when the **Protocol** needs to be revised.
 - ii. To make changes to **Protocol** fields, click the *Edit* button for that field and answer the question displayed.

- iii. Many **Protocol** fields are not available for Legacy studies (those not originally created in Quali but rather migrated from IRBManager) so you will need to provide more detailed information in the Amendment Form itself.
- b. The type and amount of information requested varies significantly based on the Protocol Type of the study being amended. The built-in logic of the form will guide you through the process once you select the Protocol Type.

B. Protocol Type & Status

- a. Select the Protocol Type for the study being amended.
 - i. **Reliance studies** generally require minimal information or revisions to the protocol but typically require submission of the amendment approval letter from the IRB of Record.
 - ii. Certain modifications to **Exempt studies** do not require IRB review and approval. These are described in [this document](#). Submit only Exempt modifications that require IRB review and approval.
 - iii. **Emergency Use of a Test Article:** the purpose of amending this type of a study is to provide information after use of the test article. This is accomplished by completing a new section of the approved **Protocol**.
- b. If displayed, indicate if the study being amended is a Legacy study, its current status and whether or not the amendment is being requested by the Sponsor. Continue to the next section.

C. Type of Change

- a. Select if the proposed amendment involves any changes to the protocol fields listed. Based on your selection (e.g., PI, Study Title, Research Personnel), specific instructions for protocol field updates, change type processes, and document requirements will display.

D. Modification Description

- a. In this section, you will provide more detailed information about the modification being requested.
- b. Answer all applicable questions and continue to the next section.

E. Study & Supporting Documents

- a. If applicable, attach any relevant or requested documents in this section.

F. Protocol Fields

- a. Edit/revise all relevant **Protocol** fields as instructed in the **Amendment Form**.

G. Submission Instructions

The Amendment can only be submitted by the PI.

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

H. PI Certification & Submission

- a. **Only after the PI has agreed with the statement of assurance should the Amendment 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”