


KUALI QUICK GUIDE

REPORTABLE EVENTS

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 Reportable Event (also referred to as Reportable New Information, RNI) that requires prompt reporting to the IRB for an approved study. It is not applicable for reporting RNIs that do not require prompt reporting to the IRB.
- C. 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 HUD Questionnaire Page.
 - b. The protocol adapts using built-in logic (smart-form) and the presentation of some questions or information is contingent on your prior responses.
 - c. **If any required fields do not have an entry, you will receive an error message identifying the empty fields.** You will not be able to move forward until you enter the missing information.
- 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 REPORTABLE EVENT 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 on “*Reportable Events*” on the bar directly below the protocol number and title.
- C.** Click “*Report an Event*” to access the **Reportable Event Form**.

III. COMPLETING & SUBMITTING THE REPORTABLE EVENT FORM

- A. How Should this RNI be Reported?**
 - a. This section of the form presents preliminary questions to determine
 - i. the type of RNI being reported,
 - ii. whether or not the RNI should be reported to the LSUHSC IRB and/or an external IRB of Record, and

- iii. whether or not the RNI should be reported using this form or a different method.
- b. Answer all questions. Based on your responses, the form will instruct you to
 - i. continue to the next section of the form;
 - ii. delete the form because the RNI does not require reporting; or
 - iii. delete the form and submit the RNI using a different method (which will be identified by the form).

B. RNI Description

- a. In this section, you will provide more detailed information about the RNI. In particular:
 - i. a description of the RNI including when it occurred and if it directly involved one or more research participants; and
 - ii. any immediate action taken to mitigate the risk to participants.
- b. Answer all questions and continue to the next section.

C. Corrective & Preventative Action

- a. Events that require prompt reporting to the IRB generally will warrant consideration of substantive changes to the research. In this section, you will:
 - i. provide your assessment of if, and what type, of changes to the research are warranted;
 - ii. describe any actions taken to correct any problem(s) responsible for the event; and
 - iii. describe any actions taken to prevent future such events.
- b. Answer all applicable questions and continue to the next section

D. Supporting Documents

- a. If applicable, attach any documents relevant to the RNI being submitted.

E. Submission

- a. Click “Submit for Review” to complete the submission and notify the IRB Office of the report.