



KABARAK UNIVERSITY
OFFICE OF THE DIRECTOR, RESEARCH, INNOVATION AND OUTREACH
RESEARCH ETHICS COMMITTEE
Reporting Undesirable Research Events Form

- The Reporting Undesirable Research Events form (RUSRE form) goes through a series of questions that will help you to determine if you need to submit the form and what information you need to provide the KUREC Board.
- The series of questions should help you to determine if it is necessary to report the incident to our office. If you determine that you need to submit the form, please submit the form within 7 days of the incident.
- To submit the document, you can email a scanned version to kurec@kabarak.ac.ke mail P.O Private Bag-20157, or submit directly to our office. Our office will review the form and advise regarding your next steps, which may include submitting a modification to your protocol/consent forms.

Study Information:

Principal Investigator Name (print)	Date
Study Title	Application Number (KUREC office only)
Principal Investigator's Signature	

Describe the event: Provide a detailed account of the undesirable event including information about the number of participants involved, what happened, the harm that occurred (if any), how the incident diverged from the proposal, and any steps you may have taken to mitigate the situation.

Question Tree

1. Does the event fit the definition of an adverse event?	Yes		No	
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<i>If yes, answer a; if no, skip to 2.</i>				
a. Is the event unexpected?	Yes		No	
<i>If yes, answer i; if no, skip to b.</i>				
i. Is the event serious?	Yes		No	
<i>If yes, answer ii; if no, skip to d</i>				
ii. Is the event occurring at a significantly higher frequency and/or severity than previously predicted?	Yes		No	
<i>If yes, submit this report. If no, skip to d.</i>				
b. Is the event serious?	Yes		No	
<i>If yes, answer c; if no, skip to d.</i>				
c. Is the event related or possibly related to the research study?	Yes		No	
<i>If yes, submit this report; if no, continue to d.</i>				
d. Does the event alter the level of risk to participants?	Yes		No	
<i>If yes or no, continue to e.</i>				
e. Does the event require you to alter the study and/or consent forms?	Yes		No	
<i>If you answered yes to d and/or e, submit this form. If you said no to both, continue to 2.</i>				
2. Does the event fit the definition of non compliance?	Yes		No	
<i>If you answered yes to 2, submit this form. If you said no, file this form for your records.</i>				

Signature of Principal Investigator		Date
Signature of Faculty Advisor (if applicable)		Date