F-1-39-8

Appendix 8 - MIRERC Unanticipated Problem Form

***An Unanticipated Problem Report must be completed immediately and forwarded to the Office of Research Ethics at MIRERC@must.ac.ke.**

***This form should only be used to describe local (internal) problems or adverse events.**[1]

Section 1			
Title of Research Study:	Click here to enter text.		
Principal Investigator:	Click here to enter text.	**Study Number:**	xxsxxxx
Supervisor: (If applicable)	Click here to enter text.	**Position:**	[i.e.: Staff, Graduate Student, Postdoctoral Fellow]
Is this study a clinical trial? * If **yes**, please see the guidance notes for this form and please fill in section below.			☐ **Yes** ☐ **No**
Sponsor:			
Please indicate if your School Supervisor has reviewed this completed form and has given their approval for you to submit this form to MIRERC. It is the responsibility of the principal investigator (PI) to ensure that all approvals are in place before this form is submitted.			☐ **Yes** ☐ **No**
Section 2			
What is the status of the study and recruitment?			
☐ Open to accrual ☐ Closed to accrual but participants are still receiving a required research intervention (drug, device, or biologic) ☐ Closed to accrual, no participants receiving a required research intervention (drug, device, or biologic) but participants are still undergoing follow-up ☐ Closed to accrual, and no participants receiving a required research intervention (drug, device, or biologic) or follow up ; data analysis is ongoing ☐ Other (please explain below)			
[If other, please provide status of study and recruitment]			
Please describe the nature of the study and synopsis of the problem:			
[Click here to provide additional information]			
Section 3			
Is the nature of the problem or event unexpected in terms of nature, severity, or frequency?			☐ **Yes** ☐ **No**

As PI, in your opinion is the unanticipated problem related to the study intervention? *If **perhaps**, please explain:	☐ **Yes** ☐ **No** ☐ **Perhaps**
Does the nature of the problem suggest that the research places participants or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, or that were not described in the original application?	☐ **Yes** ☐ **No**
Was the problem described in the Risks section of the Consent Form?	☐ **Yes** ☐ **No**
Has this type of unanticipated problem occurred in this or a related study? If **yes,** please provide details below.	☐ **Yes** ☐ **No**
[Please provide additional information]	
Has the unanticipated problem occurred previously with the same study participants? If **yes,** please describe when and how often below.	☐ **Yes** ☐ **No**
[Please provide additional information]	
Section 4	
Site of unanticipated problem: **Date & time of unanticipated problem**: **Date research team became aware of the problem**:	
How did the research team become aware of the problem?	
☐ Reported by participant ☐ Noted during chart review ☐ Reported by another health care provider ☐ Discovered by monitor/sponsor ☐ Other:	
Section 5	
Was the participant discontinued from the study as a result of the unanticipated problem?	☐ **Yes** ☐ **No**
Was medical or other intervention provided to the participant?	☐ **Yes** ☐ **No**

	☐ **Not applicable**
What action (if any) has been taken, or will be taken, by the research team and by whom, to reduce the likelihood of a future unanticipated problem?	
[Click here to provide description]	
Is this a follow-up report to an initial unanticipated problem report?	☐ **Yes** ☐ **No**
Is it a serious unanticipated problem?	☐ **Yes** ☐ **No** ☐ **Uncertain**
What adverse outcome has occurred or can be expected for the participant (for example, the participant's reputation will be harmed)?	
Please describe the current status of the participant. For example, is the participant experiencing any ongoing problems, have they recovered completely, etc.?	
Please describe below what follow-up action for study participants you recommend? *Please note that changes to study procedures or forms may require a Request for Amendment. Please consider the following options in your response: • Re-consenting current participants with an amended consent form • Informing current study participants ASAP • Revising consent/assent forms • Protocol revisions/amendment • Updating investigator's brochure • Temporarily suspending study • No actions are required	
[Click here to provide description. In addition, if any changes to forms were recommended please provide revised versions with this document]	
Has any member of your study team had any communication with the participant and if so, please describe and include this communication:	
[Click here to provide description]	