SCHOOL OF BIOMEDICAL SCIENCES
RESEARCH AND ETHICS COMMITTEE
MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

REC FORM 104

ADVERSE EVENT REPORTING FORM

Complete entire form. Do not leave any blanks

REC Protocol #:		**PI Institution :**	
Principal Investigator:		**Phone: Email:**	
Report prepared by:		**Phone: Email:**	
Study Title:			
Study Sponsor:			
Date of Adverse Event:	**Subject's Initials or Study #:**	**Type of Report:** ☐ Initial ☐ Follow-up	

Brief Description of Adverse Event (including diagnosis):

Location of Adverse Event: _____

Research involves a: ☐ Drug ☐ Device ☐ Procedure

Name of Drug, Device or Procedure:

_____

Is the drug/device investigational: ☐ Yes ☐ No

Has the Adverse Event been reported to:
☐ Sponsor, Date of report
☐ REC, Date of report _____

_____

Adverse Event appears to be (check one):
☐ Not related ☐ Unlikely ☐ Possibly related
☐ Probably related ☐ Related ☐ Unknown

Expectedness: ☐ Expected ☐ Not expected

Severity of Adverse Event:
☐ Mild ☐ Moderate ☐ Severe ☐ **Life threatening** ☐ Fatal

Outcome of Adverse Event:
☐ Death (due to event) ☐ Death (due to other causes)
☐ Hospitalization ☐ Extended Hospitalization
☐ Congenital Abnormality ☐ Recovered
☐ Not yet recovered

Recovery of Subject:
☐ Complete ☐ Moderate ☐ Minimal
☐ None ☐ Not yet resolved ☐ Unknown

Was this Adverse Event addressed in the protocol and consent form?	☐ Yes ☐ No ☐ N/A
Was this Adverse Event addressed in Investigators Brochure?	☐ Yes ☐ No ☐ N/A
Are changes required to the protocol?	☐ Yes ☐ No ☐ N/A
Are changes required to the consent form?	☐ Yes ☐ No ☐ N/A

If changes are **required**, please attach a copy of the revised protocol/consent form *with changes highlighted with a bright coloured highlighter.*

If changes are **not required**, please explain as to why changes to the protocol /consent form are not necessarily based on the event.

From the data obtained or from currently available information, do you see any need to reassess the risks and benefits to the subjects in this research. ☐ Yes ☐ No

_____
P.I. Signature Date _____

Note:

1) **Serious adverse events should be reported within 7 days while minor adverse events may be submitted in the annual report.**
2) **Soft copy of this report (SAE) should be sent to biomedicalresearch62@gmail.com**
3) **A project summary should be attached on submission of the SAE**