MAKERERE UNIVERSITY SCHOOL OF BIOMEDICAL SCIENCES RESEARCH ETHICS COMMITTEE (SBS-REC) COLLEGE OF HEALTH SCIENCES	For Office Use Only SBS-REC/A/……..…
REC FORM 107	**Date received** ……

REQUIRED FOR REPORTING
PROTOCOL VIOIATION/DEVIATION

Protocol violation: This is a deviation from the REC/IRB approved research protocol that affects research participant's rights, safety, well being, completeness, accuracy and reliability of the study data. It is therefore the principal investigator's responsibility to report protocol violation/deviation to the REC/IRB upon discovery. However violations tend to be more serious than deviation.

Note: Soft copy should be sent to this email address:biomedicalresearch62@gmail.com

REC/IRB protocol REF Number: _____

Title and Version number and date:_____

Name of researcher, _____

Organizational affiliation, _____

Date of report, _____

Date(s) when violation occurred, _____

Brief description of what happened, _____

Any effect on the study, _____

Any adverse events arising from the violation, _____

Management and follow up of violation and steps to avoid recurrence of the violation.

Notification to the REC and where applicable the collaborating organization's REC or any other regulatory bodies should be made by the researcher within seven (7) calendar days of becoming aware of the event.

Type of Protocol Violation/Deviation

Major violation/deviation; one that may impact subject safety; any factor determined by REC/IRB Chair or REC/IRB member as warranting review of the violation by the convened REC/IRB. For example:

☐ Failure to obtain informed consent i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures
☐ Enrollment of a subject who did not meet all inclusion/exclusion criteria
☐ Performing study procedure not approved by the REC/ modifications
☐ Screening procedure required by protocol not done
☐ Failure to report serious unanticipated problems/adverse events involving risks to subjects to the REC/IRB
☐ Failure to perform a required lab test that may affect subject safety or data integrity
☐ Drug/study medication dispensing or dosing error
☐ Study visit conducted outside of required time frame that, in the opinion of the PI or IRB, may affect subject safety
☐ Failure to follow safety monitoring plan
☐ Other (Specify):_____

Minor violation/deviation; one that does not impact subject safety or does not substantially alter risks to subjects. For example:

☐ Implementation of unapproved recruitment procedures
☐ Missing original signed and dated consent form (only a photocopy available)
☐ Missing pages of executed consent form
☐ Inappropriate documentation of informed consent, including:
  - o missing subject signature
  - o missing investigator signature
  - o copy not given to the person signing the form
  - o someone other than the subject dated the consent form
  - o individual obtaining informed consent not listed on REC approved study personnel list

☐ Use of invalid consent form, i.e., consent form without REC approval stamp or outdated/expired consent form
☐ Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity;
  - o Study procedure conducted out of sequence
  - o Omitting an approved portion of the protocol
  - o Failure to perform a required lab test
  - o Missing lab results
  - o Enrollment of ineligible subject (e.g., subject's age was 6 months above age limit)
  - o Study visit conducted outside of required timeframe

☐ Over-enrollment
☐ Enrollment of subjects after REC-approval of study expired or lapsed;
☐ Failure to submit continuing review application to the REC before study expiration.

Detailed description of Protocol Violation/Deviation:

_____
_____
_____
_____

Corrective Action:
☐ Patient withdrawn
☐ Patient remains on study but data analysis will be modified
☐ Study Sponsor notified: Date:_____
☐ Other:_____

Preventive Action (What actions have been put in place to ensure that such violations do not happen in future).

Person Reporting

Name: _____

Signature_____

Date(dd/mm/yyyy)_____