MAKERERE UNIVERSITY SCHOOL OF HEALTH SCIENCES RESEARCH & ETHICS COMMITTEE (MakSHS-REC) COLLEGE OF HEALTH SCIENCES	**For Office Use Only** **MakSHS-REC/A/……..…**
REC FORM 105	**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 upon discovery. However, violations tend to be more serious than deviation.

Note: Submit the report via NRIMS on: https://nrims.uncst.go.ug/

Also send to this email address: healthsciences.irb@gmail.com

Name of the Principal Investigator: _____

Organization of affiliation: _____

REC/IRB protocol REF Number: _____

_

Title and Version number and date: _____

Subject ID#:_____

Date of report to MAKSHSREC: ____dd/mm/yyyy_____

Date (s) when Violation/Deviation occurred: ___dd/mm/yyyy_____

Type of Protocol Violation/Deviation

Major violation/deviation; one that may impact subject safety; any factor determined by REC Chair or REC 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 research participant who did not meet all inclusion/exclusion criteria
☐ Enrollment of more research participants in the study more than the approved targeted number
☐ Performing study procedure not approved by the IRB/ modifications
☐ Screening procedure required by protocol not done
☐ Failure to report serious unanticipated problems/adverse events involving risks to subjects to the REC
☐ 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 REC, 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 IRB before study expiration.

Detailed description of Protocol Violation/Deviation (what happened)

Any effect on the stud
_____

Any adverse events arising from the violation and 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 occur in future).

Person Reporting

Name:_____

Signature_____

Date(dd/mm/yyyy)_____