Study Specific Procedure	**SSP No:**013 **Version No:** 2.0 **Supersedes:** 1.0 **Effective Date:**

Title: Protocol Deviation/Violation SSP			
	NAME	**SIGNATURE**	**DATE**
REVIEWING AUTHORITY	Isaiah Njagi		
QUALITY ASSURANCE AUTHORITY	Aisha Bwika		
APPROVING AUTHORITY	Caroline Ogwang		

1.0 PURPOSE

This SOP provides guidance for timely reporting of protocol deviations or violations for the FLACSAM study.

2.0 SCOPE / RESPONSIBILITY:

This SOP applies to the study clinicians and nurses in the FLACSAM study. Overall responsibility for reporting of any deviation or violation from the study protocol lies with the principal investigator through the lead clinician.

3.0 DEFINITIONS /ABBREVIATIONS

3.1 Protocol Deviation: Any change, departure from the study procedures of the FLACSAM study protocol that is under the investigator's control and that has not been approved by the IRB. Examples that will apply to the FLACSAM study include:

- Wrong dose of medication given

3.2 Protocol Violation: A protocol violation is a deviation from the IRB approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy, and reliability of the study data. Examples of this include but are not limited to;

- Failure to obtain informed consent (i.e. no documentation in source data or an Informed Consent form)
- Enrolment of subjects that do not meet the inclusion/exclusion criteria
- Administration of incorrect study medication

3.3 CRF: Case Report Form

3.4 FLACSAM: First Line Antimicrobials in Severe Acute Malnutrition

3.5 ICH GCP: International Conference on Harmonisation Good Clinical Practice

3.6 IRB: Institutional Review Board

3.7 KEMRI: Kenya Medical Research Institute

3.8 SAE: Serious Adverse Event

3.9 SSP: Study Specific Procedure

4.0 MATERIALS NEEDED:

- Protocol deviation/ violation form (see appendix).

5.0 METHODOLOGY

1. Deviations related to study drug administration have potential to impact on the results of the study for example:
    a. Wrong dose given – This could either be under dose or overdose. The lead clinician at the site must be notified first of the deviation. Subsequently, notification to the P.I/designees should be done by the site's lead clinician or directly by the attending/available clinician.
2. Violations to the protocol that include enrolling ineligible participants or enrolling a participant without following due process of informed consent requires immediate reporting to the P.I through the lead clinician. The affected participant may be required to be withdrawn from the study and the event will be reported to the ethics committee.
3. Complete the protocol deviation and violation forms appropriately and file in the investigator site file.
4. Centrally in Kilifi, a listing of all deviations and violations coming from sites will be kept for record and monitoring of trends to inform on remedial action and need for retraining as appropriate.

6.0 APPENDICES

6.1 Protocol Deviation/ Violation Form

PROTOCOL DEVIATION AND VIOLATION LOG

Protocol Title: First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

Event Date	Study No.	Event Description	Subject withdrawn? Y/N	Reason/Action Taken to Avoid Recurrence	Initials

Investigator's/ nominee Name _____ Signature _____ Date (dd/mm/yyyy) _____

7.0 REFERENCES

1. FLACSAM Protocol

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: **Protocol deviation/violation SOP**	Dated: **13th Jul 2017**	SOP No.: **013**	No. Pages: **4**
Version 2.0: Title: **Protocol deviation/violation SSP**	Dated:	SOP No.: **013**	No. Pages: **5**

SOP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW
26/11/2019	Isaiah Njagi		• Periodic SOP review • Adopted the SSP template.
26/11/2019	Isaiah Njagi		• Removed Nancy Kagwanja as the preparer of the SSP

SSP Awareness Log

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfilment of Good Clinical Practice (GCP).

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