Study Specific Procedure	**SOP No:** 014 **Version No:** 2.0 **Supersedes:** 1.0 **Effective Date:**

Title: Metronidazole or placebo bottle replacement procedure

	NAME	SIGNATURE	DATE
PREPARER	Caroline Ogwang		
REVIEWING AUTHORITY	Isaiah Njagi		
QUALITY ASSURANCE AUTHORITY	Aisha Bwika		
APPROVING AUTHORITY	Mainga Hamaluba		

1.0 PURPOSE / INTRODUCTION:

The purpose of this SSP is to describe the process of replacing of metronidazole/placebo in case of loss or damage of the investigational product. This applies to only FLACSAM trial participants.

2.0 SCOPE / RESPONSIBILITY

2.1 This SSP applies to all study clinicians, nursing staff and field workers involved in the management of study participants, the clinical lead, study coordinator and statistician.

2.2 The Principal Investigator through the lead clinician retains the overall responsibility on implementation of this SSP.

3.0 DEFINITIONS

3.1 **IP:** Investigational Product

3.2 **SSP:** Study Specific Procedure

4.0 EQUIPMENT / MATERIALS

4.1 Designated numbered replacement metronidazole/placebo bottles

4.2 Drug replacement log

4.3 Pens

5.0 METHODOLOGY:

5.1 Introduction and general considerations

5.1.1 In the FLACSAM study the clinician, nurses and fieldworkers are blinded to metronidazole/placebo IP allocation. This has been done by manufacturing and packing metronidazole and placebo similarly (appearance, glass bottles, type of packaging and anonymized labelling). They have then been assigned and labelled with study numbers according to the randomisation list.

5.1.2 The IP may be affected by incidents during the study such as spills and breakage either before or after allocation to a participant.

5.1.3 The procedure in this SOP will guide the replacement of a metronidazole/placebo bottle to ensure that integrity of randomisation is not affected. The procedure aims to ensure

that the participant receives the correct allocation and doses for the duration stipulated in the protocol.

5.2 Preparation

5.2.1 Prospectively, the study coordinator or clinical lead, in consultation with the statistician who conducted the randomisation, shall allocate a pool of numbered bottles to be used for replacement in case of loss or damage from specific randomisation blocks from the end of randomisation list of the available randomised and labelled bottles. These replacement bottles shall be allocated to the study sites.

5.3 Metronidazole or Placebo replacement

5.3.1 In case of any incident that may affect the integrity of IP, a study clinician/study nurse should inform the study co-ordinator or clinical lead immediately by telephone.

5.3.2 The study clinician/study nurse shall also contact the site statistician/designee stating the CRF/study number affected and request for the number of a replacement for the affected metronidazole/placebo bottle.

5.3.3 The statistician will assign a numbered replacement bottle with the same allocation (metronidazole/placebo) to that the patient had been earlier randomly assigned to and email it to the study staff requesting the replacement, copied to the clinical lead and study coordinator.

5.3.4 The study clinician/nurse and a witness (another member of the study team) will pick the newly assigned number and countercheck that it corresponds with what has been assigned by the statistician and that it is also replacing the number that had been given to the statistician.

5.3.5 The new bottle will then be taken from its box and labelled with the participant's earlier number. The study clinician will do this by crossing out the number already on the replacement bottle, leaving it visible, and writing the participant's allocated number, their initials and date in the presence of the witness and put it in the patient's earlier drug box that has the initial assigned randomisation number. The new box will be kept safe by the study team on site and be periodically sent back to the study coordinator using a log; this may be done after monitoring.

5.3.6 The two study team members will then complete the metronidazole/placebo replacement log with the following information: the randomisation number for the bottle affected, the randomisation number for the replacement bottle, state the nature of the incident that affected the drug bottle, and both put their initials and date

6.0 APPENDICES

6.1 Appendix 1: Drug Replacement Log

KEMRI | Wellcome Trust
Clinical Trials

TITLE: Drug Replacement Log SOP No: 014 Version: 1.0 dated: 06th Dec 2017

First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition
Site: _____

FLACSAM METRONIDAZOLE/PLACEBO REPLACEMENT LOG

Date (dd/mm/yyyy)	Randomization number for affected drug bottle	Randomization number for replacement drug bottle	Reason for replacement	Checked by 1(Staff Initials)	Checked by 2(Staff initials)

7.0 REFERENCES

FLACSAM Protocol

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1 Title: **Metronidazole/placebo bottle replacement in case of accidental loss or damage**	Dated: **07th Dec 2017**	SOP No.:**014**	No. Pages: **5**
Version: 2 Title: **Metronidazole or Placebo replacement procedure**	Dated:	SOP No.:**014**	No. Pages: **6**
Version: Title:	Dated:	SOP No.:	No. Pages:

SOP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW
26th Nov 2019	Isaiah Njagi		• Periodic SOP review • Adopted the SSP template • Changed name of the SOP from: *Metronidazole/placebo bottle replacement in case of accidental loss or damage to Metronidazole or Placebo replacement procedure*

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).

Number	Name	Signature	Date (dd/mmm/yyyy)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			