# Study Specific Procedure	**SSP No:** 010 **Version No:** 2.0 **Supersedes:** 1.0 **Effective Date:**

Title: Drug Accountability Procedure			
	NAME	**SIGNATURE**	**DATE**
REVIEWING AUTHORITY	Isaiah Njagi		
Q.A AUTHORITY	Aisha Bwika		
APPROVING AUTHORITY	Caroline Ogwang		

1.0 PURPOSE

This SSP outlines the procedural steps for study drug management. It aims to ensure appropriate

implementation of specific drug accountability procedures of the study protocol across all study sites.

2.0 SCOPE / RESPONSIBILITY:

2.1 The principal investigator or designee has the ultimate responsibility for the accountability of the study drugs.

2.2 The trial coordinator, the pharmacist, study clinicians and study nurses are responsible for keeping accurate records with sufficient information to provide a full audit trail from the receipt of the study products to their removal from site or destruction.

3.0 ABBREVIATIONS

CGH	Coast General Hospital
KCH	Kilifi County Hospital
KEMRI	Kenya Medical Research Institute
SSP	Study Specific Procedure

4.0 MATERIALS NEEDED

4.1 Lockable storage cabinets.

4.2 Study files

4.3 Drug accountability log

4.4 Drug shipment records

5.0 METHODOLOGY

a) Introduction

1. Before study start all study, drugs will be kept by the clinical trial pharmacy. The clinical trial pharmacy will maintain drug shipment records as well as a temperature log to ensure that the drugs are maintained in the appropriate temperature.

2. At study initiation, all drugs will be issued to study sites by the pharmacist at the clinical trials pharmacy through the study coordinator. Documentation of the drugs issued to the sites will be maintained by the pharmacist at the clinical trials office. The study sites will also maintain documentation of drugs received at site.

b) Accountability for study drugs at Kilifi County Hospital

1. Kilifi County Hospital will use the clinical trial pharmacy for storage of study drugs.
2. In the wards the study drugs will be stored separately from normal stock in a drug cabinet with restricted access.
3. Documentation of drug movement between the pharmacy and the ward will be completed in separate drug accountability logs for ceftriaxone (reflecting the various strengths-500mg and 1000mg, penicillin-1MU and 4MU, gentamicin and metronidazole/placebo (See drug accountability log).

c) Accountability for study drugs at study site (Coast General and Mbagathi Hospitals):

1. Mbagathi Hospital and CGH will utilize the clinical trial office for storage of drugs.

2. Study drugs, ceftriaxone, gentamicin and penicillin will be received in the sites' clinical trial office by the study staff. Upon receipt of the study drugs, ensure that the information on the drug shipment log (appendix 6.1) matches exactly with what has been sent to site, including, Lot/Batch Number and quantity. The receiving study staff will sign on the drug shipment log after confirmation.

3. The study drugs will be collected from the clinical trial office/pharmacy for use in the ward by the study nurse. Documentation of drug movement between the clinical trial office and the ward will be completed in separate drug accountability logs for ceftriaxone (reflecting the various strengths-500mg and 1000mg, penicillin-1MU and 4MU, gentamicin and metronidazole/placebo (Appendix 6.2).

d) All sites

4. The metronidazole and placebo drugs will be received at study sites already pre-labelled with a randomization number.

5. After determining which arm a participant has been randomized to, the intravenous drugs (either ceftriaxone or penicillin and gentamicin) will be obtained from a common pool of drugs.

6. The Intravenous drug dispensing log (Appendix 6.3) will be documented after every drug round. The oral drug dispensing log (Appendix 6.4) will be documented when Metronidazole/placebo are first picked for the patient. During subsequent use, no entries into the dispensing log will be made for the oral drugs. The drug vial and bottle will be retained for checking during drug accountability assessment by study monitors

7. If the patient goes away with the metronidazole bottle on discharge, clear instructions will be given for the patient to return the bottle on Day 14 follow-up.

8. If a participant in the penicillin-gentamicin arm requires ceftriaxone as a second line drug, they will receive a generic alternative different from what will be dispensed in the ceftriaxone arm.

6.0 APPENDICES

Appendix 6.1: Study drug reception log

FLACSAM STUDY SHIPMENT LOG
SITE :

Ceftriaxone			**Penicillin**		**Gentamicin**	**Metronidazole/Placebo**	**Issued by (Pharmacy Staff Initials)**	**Checked by (Staff Initials)**	**Received by (Staff Initials)**
Batch No:			**Batch No:**		**Batch No:**	**Batch No:**			
Expiry:			**Expiry:**		**Expiry:**	**Expiry:**			
Date Dd/mm/yyyy	Strength in Mg	No of vials	Strength in MU	No of vials	Number of vials	No. of bottles			

Appendix 6.2 Study Drug Accountability Log

Drug:					
Strength:		**Batch:**		**Expiry date:**	
Date:	**Opening balance:**	**Received**	**Issued**	**Total in hand**	**Staff initials**

Appendix 6.3 Drug Dispensing Log

INTRAVENOUS DRUG DISPENSING LOG **SITE: _____**						
Date (ddmmyyyy)	**Time (24HR)**	**Study ID**	**Drug**	**Strength**	**Quantity Used**	**Staff Initials**
SUMMARY OF QUANTITIES USED						
CEFTRIAXONE 500MG	**CEFTRIAXONE 1000MG**	**BENZYLPENICILLIN 1MU**	**BENZYLPENICILLIN 5MU**			

Appendix 6.4 Oral Drug Dispensing Log

Drug: Metronidazole 200mg/5ml or Placebo **SITE:**_____				
Date (ddmmyyyy)	**Time (24HR)**	**Study ID**	**Quantity Issued**	**Staff initials**
SUMMARY OF QUANTITIES USED:				
Metronidazole 200mg/5ml or Placebo				

7.0 REFERENCES

FLACSAM study protocol.

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1: Title: Drug Accountability SOP	Dated:13/07/2017	SOP No.010	No. Pages: 8
Title: Drug Accountability SSP	Dated: 26/11/2019	SSP No. 010	No. Pages: 9

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).

Number	Name	Signature	Date (dd/mmm/yyyy)
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