



<b>Study Specific Procedure</b>			SSP No: 006 Version No: 2.0 Supersedes: 1.0 Effective Date:
<b>Title: Rectal swab and whole stool collection SSP</b>			
	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWING AUTHORITY</b>	Robert Musyimi		
<b>QA UNIT AUTHORITY</b>	Aisha Bwika		
<b>APPROVING AUTHORITY</b>	Caroline Ogwang		

**1.0. PURPOSE/INTRODUCTION:**

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The purpose of this SSP is to describe the procedure to be followed when collecting a rectal swab sample from FLACSAM study participants.

### 2.0. SCOPE / RESPONSIBILITY:

This SSP applies to study clinicians, nurses and field workers. The overall responsibility for ensuring collection of quality samples lies with the principal investigator through the lead clinician.

### 3.0. DEFINITIONS / ABBREVIATIONS

- 3.1. **FC:** Faecal Carriage
- 3.2. **OPD:** Outpatient Department
- 3.3. **SAM:** Severe Acute Malnutrition
- 3.4. **SSP:** Study Specific Procedure

### 4.0. EQUIPMENT/ MATERIALS/ REAGENTS

- 4.1. Gloves
- 4.2. Transport swab with Amies transport medium on a flexible plastic shaft
- 4.3. Dry floc swabs on a flexible plastic shaft
- 4.4. Lab request form
- 4.5. Normal saline (0.9 NaCl) in single-use aliquots
- 4.6. Tissues
- 4.7. Ziploc bag
- 4.8. Cool box with ice packs and thermometer
- 4.9. Stool collection pot with a scoop
- 4.10. Clean gauze (for those passing very water stool)
- 4.11. Specimen container
- 4.12. Laboratory request form

### 5.0. METHODOLOGY FOR RECTAL SWAB COLLECTION

#### 5.1 Collection of Rectal swabs

##### Introduction

1. A rectal swab will be taken from eligible study participants with and without SAM who are admitted to hospital with a syndrome requiring antimicrobial treatment under the current national guidelines. This will be done at the point of

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admission (Paediatric Wards / OPD) or the clinic where scheduled follow up visits will be carried out.

**N/B:** Non- SAM participants will have samples taken only at admission and discharge and will not be followed up by the study.

2. When performed correctly, rectal swabbing is a low risk procedure that can safely be performed in a routine procedure room or at the bedside. 2 rectal swabs will be taken at admission, discharge, day 45, and day 90 and for readmissions (at admission and discharge.)
3. The discharge rectal swab should be collected as close as possible to when a child leaves the hospital; a child might not leave the hospital on the same day of discharge. However, if it is not possible to predict when the child will leave the hospital the clinician should take the sample after a decision has been reached that the child should be discharged following a ward round and this date will be entered as the discharge date.

## 5.2 Collection of Rectal Swabs- Procedure

1. Prepare all equipment before starting the procedure and label the swab with the serial number, time point and date of sample collection. Wash your hands and put on gloves
2. Lay the child across his parent/guardian's lap or on a mattress.
3. Collect 2 samples. The first swab will be a dry swab and the second swab will be a wet swab.
4. Open the swab (do not touch the tip or shaft of the swab, hold it only by the handle). Gently insert the tip of the swab just inside the rectum (i.e. slightly past the anal sphincter) and rotate 180 degrees and back again 2 or 3 times.
5. For the wet swab, moisten the tip with a drop of saline prior to insertion into the rectum.
6. Place the swabs inside the transport tube into the transport medium and close.
7. Provide tissue if needed to the parent/guardian and discard the remaining sterile water or saline. This must never be reused. Remove gloves and wash your hands

8. Fill out the specific rectal swab laboratory request form (one for each rectal swab) and transport the specimen (at room temperature) to the laboratory for processing as soon as possible. If this will not be possible within 2 hours, such as overnight/ due to any other reason during the day, then keep the swab at fridge temperature (2°-8°C) before transporting to the laboratory within 24 hours of collection. Document on the CRF the date and time the sample was collected.

### 5.3 Collection of whole stool sample

#### **Introduction**

1. Whole stool samples will be collected at discharge and at day 45. If a child does not pass stool during their scheduled visit, no additional rectal swabs will be collected.
2. When discharge is anticipated to occur on the next day; the mother can be given a stool pot and scoop up to collect a stool sample the day before discharge (a stool sample can be collected up to 2 days before discharge).
3. The mother will be given a stool pot and scoop on the day 14 visit and asked to come with a stool sample collected in the morning of their day 45 visit if produced. Samples should not be collected the day before; must be only same day samples.

### 5.4 Collection of the whole stool sample- Procedure

1. Provide guidance to the caretaker on how and when to collect a stool sample and supply necessary stool container and scoop.
2. Ask the caretaker to fill about half of the container with stool using the scoop provided with the container (show scoop).
3. Ask her or him after collection to tightly close the container and to bring the sample to the admission/procedure/clinic visit room and alert a study staff as soon as possible.
4. For patients with watery stools, provide the caretaker with stool pot together with parafilm gauze and ask the caretaker to line the child's diaper with the parafilm. Once the gauze is soiled it should be folded and put into the stool pot.

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5. In the situation where the caretaker has difficulty getting stool sample, a rectal swab should be taken by a member of the study.
6. Wear disposable gloves when receiving the stool sample from the caretaker. Always ensure the stool container is tightly closed before transporting to the laboratory.
7. Once the stool sample has been collected, fill in the request form and take to the lab immediately.

### 6.0 APPENDICES:

None

### 7.0 REFERENCES:

- 7.1 Nursing Times 20 May 2008 Vol 104 No 20 [www.nursingtimes.net](http://www.nursingtimes.net).
- 7.2 FLACSAM protocol

### 8.0 DOCUMENT CHANGE HISTORY

#### Version Table:

Version 1.0: Title: <b>Rectal Swab and whole stool collection SOP</b>	Dated: <b>13<sup>th</sup> Jul 2017</b>	SOP No. <b>006</b>	No. Pages: <b>5</b>
Version 2.0: Title: <b>Rectal Swab and whole stool collection SSP</b>	Dated: <b>26<sup>th</sup> Nov 2019</b>	SSP No. <b>006</b>	No. Pages: <b>6</b>

#### SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW
26/11/2019	Robert Musyimi		Periodic SOP review Adopted the SSP template
02 <sup>nd</sup> Dec 2019	Aisha Bwika		Removed Joseph Waichungo as the preparer of this SOP.

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**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 fulfillment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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