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|------------------------------------|-----------------|------------------|--|
| <b>Study Specific Procedure</b>    |                 |                  | <b>SSP No: 001</b><br><b>Version No: 2.0</b><br><b>Supersedes: 1.0</b><br><b>Effective Date:</b> |
| <b>Title: Screening Procedure</b>  |                 |                  |  |
|                                    | <b>NAME</b>     | <b>SIGNATURE</b> | <b>DATE</b>  |
| <b>REVIEWING AUTHORITY</b>         | Isaiah Njagi    |                  |  |
| <b>QUALITY ASSURANCE AUTHORITY</b> | Aisha Bwika     |                  |  |
| <b>APPROVING AUTHORITY</b>         | Caroline Ogwang |                  |  |

**1.0 PURPOSE**

This SOP describes the process of screening sick children requiring hospital admission - for eligibility in the FLACSAM trial at 4 hospital sites.

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## 2.0 SCOPE / RESPONSIBILITY:

2.1 This SOP applies to FLACSAM study field workers, nurses and clinicians involved in the screening of sick children being admitted at study hospitals.

2.2 The Principal Investigator retains overall responsibility on implementation of these standards and recruitment of suitable participants into the study.

## 3.0 DEFINITIONS/ ABBREVIATIONS:

- 3.1 CRF: Case Report Form
- 3.2 MUAC: Mid-Upper Arm Circumference
- 3.3 SAM: Severe Acute Malnutrition
- 3.4 PK: Pharmacokinetics
- 3.5 OPD: Outpatient Department
- 3.6 SD: Standard Deviation
- 3.7 SOP: Standard Operating Procedure
- 3.8 WHZ: Weight for Height z-score

## 4.0 MATERIALS

- 4.1 – MUAC Tape
- 4.2 – Weighing Scale
- 4.3 – Length Board/Stadiometer
- 4.4 – WHZ calculator

## 5.0 METHODOLOGY:

### 5.1 Introduction

- a) Screening of patients will be done at the point of admission (i.e. OPD /casualty/ paediatric ward) before the child receives the first dose of antibiotics.
- b) For purpose of this study, SAM will be defined as:

Children 2 to 5 months old:

- MUAC <11 cm and weight >2.5kg or
- WHZ <-3 SD and weight >2.5kg or,
- Kwashiorkor

Children 6 to 59 months old:

- MUAC <11.5cm, or
- WHZ <-3 SD, or
- Kwashiorkor

Children aged 60months to 13 years:

- BMI-for-age Z score <-3 or
- MUAC <11.5cm
- Kwashiorkor

## 5.2 Trial participants

1. All children admitted with severe acute malnutrition will be screened for eligibility at the point of admission. This will be done before administration of the first dose of antibiotics. However, if a child has already received one dose of the medication, the child will still be considered eligible in to the trial.
2. Inclusion Criteria for trial study participants
  - a) Age 2months to 13 years inclusive
  - b) SAM
  - c) Admitted to hospital and eligible to receive intravenous antibiotics according to the current national guidelines.
  - d) Planning to remain within the hospital catchment area and willing to come for specified visits during the 90 day follow up period
  - e) Informed consent provided by the parents/guardian
3. Exclusion criteria for trial study participants
  - (a) Refusal of consent.
  - (b) Known allergy or contraindication to penicillin, gentamicin, ceftriaxone or metronidazole
  - (c) A specific and documented clinical indication for another class of antibiotic
  - (d) Previously enrolled in this study
4. All sick children with SAM requiring admission will be entered in the screening log (Appendix 1) by a field worker during screening.
5. Assessment of eligibility (inclusion and exclusion) will be a shared responsibility of the study staff.
6. Eligible participants must be reviewed by the study nurse/ clinician or designee for exclusion before approaching parent/carer to obtain an informed consent for the study.

## 5.3 For Antimicrobial pharmacokinetics (PK)

- 5.3.1 The PK study component will involve SAM sick children requiring hospitalization and intravenous antibiotics as part of their treatment.
- 5.3.2 During the PK study, all SAM children enrolled into the PK study (n=120) will also be participants in the main trial.

5.3.3 **Inclusion criteria** for PK:

- (a) A convenience sample of the children with SAM enrolled in the trial during normal working hours

5.3.4 Similar exclusion criteria for PK study will apply as for the other SAM trial participants

- a) Refusal of consent. (Refusal of consent for the PK study will not imply refusal of consent for the main trial).
- b) Known allergy or contraindication to penicillin, gentamicin, ceftriaxone or metronidazole
- c) A specific and documented clinical indication for another class of antibiotic
- d) Previously enrolled in this study

**5.4 Fecal Carriage Non-Trial Participants (Non-SAM)**

5.4.1 Participants without SAM will be recruited into the study as non-trial participants for faecal carriage. Inclusion criteria:

- a) Age 2 months to 13 years inclusive
- b) Without SAM (as defined above)
- c) Admitted to hospital and eligible for intravenous antibiotics according to WHO guidelines
- d) Informed consent provided by the parents/guardian

5.4.2 Exclusion criteria for fecal carriage non-trial participants

- a) Previously enrolled in this study
- b) Refusal of consent

5.4.3 During enrolment for Fecal Carriage, each child with SAM enrolled into the trial will be matched with a child without SAM. A separate screening log will be used for the SAM trial participants and the non-SAM non-trial participants.

*NOTE: If a potential study participant is so sick that it is difficult to introduce the study/consent the guardian/parent, clinical care will supersede enrolment into the trial. The guardian/parent can be consented later and the child enrolled into the study if they have received only one dose of antibiotics. If they are not approached for consent this will be documented in the screening log and a comment made on the reason for failure to enroll.*

## 6.0 APPENDICES

### 6.1 Screening log for main trial

#### SCREENING LOG FOR FLACSAM TRIAL PARTICIPANTS

**SITE:**

| Screening no | Screening date DD/MM/YYYY | Patient name | Hospital No | DOB DD/MM/YYYY | Age in mths | MUAC (cm) | Weight (kg) | Height (cm) | Weight for height Z score | Oedema Y/N | BMI for age | Eligibility code | Consent 1-Agreed,2-Refused, 3-Not Approached | Enrolment code | Comments | Staff Initials |
|--------------|---------------------------|--------------|-------------|----------------|-------------|-----------|-------------|-------------|---------------------------|------------|-------------|------------------|--|----------------|----------|----------------|
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**Eligibility Codes:**

- 1-Eligible
- 2-Known allergy or contraindication to penicillin, gentamicin, ceftriaxone or metronidazole
- 3- Specific and documented clinical indication for another class of antibiotic
- 4-Previously enrolled
- 5-Lives outside Catchment area
- 6-Other

**Enrolment codes**

- 1-Enrolled
- 2-Died before enrolment
- 3-Absconded
- 4-Withdrew consent
- 5-Other

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**6.2 Screening log for FC study (Non-SAM participants)**

**SCREENING LOG FOR FLACSAM FC Study (Non-SAM participants)**

SITE: \_\_\_\_\_

| Screening no | Screening date (DD/MM/YYYY) | Patient name | Hospital No | DOB (DD/MM/YYYY) | Age (mths) | MUAC (cm) | Weight (kg) | Height (cm) | Weight for height Z score | Oedema Y/N | BMI for age | Eligibility code | Consent 1-Agreed, 2-Refused, 3-Not Approached | Enrolment code | Comments | Staff Initials |
|--------------|-----------------------------|--------------|-------------|------------------|------------|-----------|-------------|-------------|---------------------------|------------|-------------|------------------|---|----------------|----------|----------------|
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**Eligibility codes**

- 01: Eligible
- 02: Does not require IV antibiotics
- 03: Previously enrolled in this study
- 04: Other

**Enrolment codes**

- 01- Enrolled
- 02- Died before enrolment
- 03- Absconded before enrolment
- 04- Withdrew Consent
- 05- Other

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**STUDY:** FLACSAM

**SSP TITLE:** Screening Procedure **SSP No:** 001 **Version:** 2.0 **dated** .....

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**7.0 REFERENCES:**

- FLACSAM protocol

**8.0 DOCUMENT CHANGE HISTORY**

**Version Table:**

|  |  |                    |                        |
|--|--|--------------------|------------------------|
| Version 1:0<br>Title: <b>Screening SOP</b>       | Dated: <b>13<sup>th</sup> Jul 2017</b> | SOP No. <b>001</b> | No. Pages: <b>8</b>    |
| Version 2.0<br>Title: <b>Screening Procedure</b> | Dated: <b>25<sup>th</sup> Nov 2019</b> | SSP No. <b>001</b> | No. of pages: <b>9</b> |

**SSP Review and Updating Logs**

| DATE                      | NAME OF REVIEWER | SIGNATURE | REASON FOR REVIEW                                    |
|---------------------------|------------------|-----------|--|
| 25 <sup>th</sup> Nov 2019 | Isaiah Njagi     |           | Periodic Review and adoption of the new SSP template |
| 25 <sup>th</sup> Nov 2019 | Isaiah Njagi     |           | Removed Nancy Kagwanja as the preparer of the SSP    |
|                           |                  |           |  |

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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 fulfilment of Good Clinical Practice (GCP).

| Number | Name | Signature | Date (dd/mmm/yyyy) |
|--------|------|-----------|--------------------|
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