1. **PURPOSE**

This SOP describes the process of screening sick children requiring hospital admission for eligibility in the PB-SAM trial. Screening, giving information, consent and recruitment according to the inclusion and exclusion criteria will take place at admission to the hospital admission or within 72 hours of admission.

1. **SCOPE / RESPONSIBILITY:**
   1. This SOP applies to PB-SAM study field workers, nurses and clinicians involved in the screening of sick children being admitted or already admitted at study hospitals.
   2. The Principal Investigator retains overall responsibility on implementation of these standards and recruitment of suitable participants into the study.
2. **DEFINITIONS/ ABBREVIATIONS:**

**3.1** **CRF:** Case Report Form

**3.2** **MUAC:** Mid-Upper Arm Circumference

**3.3** **SAM:** Severe Acute Malnutrition

**3.5** **OPD:** Outpatient Department

**3.6** **SD:** Standard Deviation

**3.7** **SOP:** Standard Operating Procedure

**3.8** **WHZ:** Weight for Height z-score

1. **MATERIALS**
   1. – MUAC Tape
   2. – Weighing Scale
   3. – Length Board/Stadiometer
   4. – WHZ calculator
2. **METHODOLOGY:**
   1. **Introduction**
3. Screening of patients will be done at the point of admission (i.e. OPD /casualty/ Paediatric ward) during admission process or within 72 hours after admission.
4. For purpose of this study, SAM will be defined as:

Children below 6 months old:

* MUAC <11 cm
* WHZ <-3 SD
* Symmetrical oedema of at least the feet related to malnutrition

Children 6 to 59 months old:

* MUAC <11.5cm,
* WHZ <-3 SD
* Symmetrical oedema of at least the feet related to malnutrition
  1. **Trial participants**

1. All children admitted with severe acute malnutrition will be screened for eligibility at the point of admission or within 72 hours after admission in the ward.
2. Inclusion Criteria for trial study participants
   1. Age ≥2 to <59 months
   2. Admitted to hospital with an acute, non-traumatic illness and within 72 hours of admission at the time of enrolment
   3. Severe malnutrition (weight-for-height <-3 z scores of the median WHO growth standards and/or mid upper arm circumference <115mm (<110mm age below 6 months), or symmetrical oedema of at least the feet related to malnutrition (not related to a primary cardiac or renal disorder)
   4. Presence of two or more features of severity as specified in ***table 1*** below.

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| **Clinical/Lab Feature** | **Criteria** |
| Respiratory distress | “Subcostal indrawing” or “nasal flaring” or “head-bobbing” |
| Oxygenation | “Central cyanosis” or SaO2 <90% |
| Circulation | capillary refill >3 seconds |
| Conscious level (AVPU) | < “A” |
| Pulse | > 180 per min |
| Haemoglobin | < 7g/dl |
| Blood glucose | < 3mmol/L |
| White blood cell count | < 4 or > 17.5 x 109/L |
| Temperature | <36 or >38.5oC |
| Very low MUAC | MUAC <11cm |

Table 1. Severity features, two or more are required for enrolment

* 1. Accompanied by care provider who provides written informed consent

Primary caregiver plans to stay in the study area during the duration of the study.

1. Exclusion criteria
   1. Requires immediate cardiac/respiratory resuscitation (may be re-evaluated for study eligibility within 72h of admission)
   2. Presence of terminal illness (other than severe acute malnutrition) likely to result in death within 6 months in the opinion of the recruitment team
   3. Known congenital heart disease
   4. Admission for traumatic or surgical indication
   5. Known liver disorder or exocrine pancreatic disorder – e.g. biliary atresia, history of gallstones, cystic fibrosis or clinical jaundice
   6. Known stomach or duodenal ulcer
   7. Residence is outside the catchment area of study hospital
   8. Primary caregiver declines to provide informed consent
   9. Known intolerance or allergy to any study medication

***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 within 72 hours after admission. 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.*

1. **APPENDICES**
   1. **Screening Log for PB-SAM Participants**

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| Screening No. | Screening date | Patient Name | Hospital No. | Date of birth | Age in months | MUAC in cm | Weight in Kg | Height in cm | WHZ-score | Oedema (Yes or No) | “Subcostal indrawing” or “nasal flaring” or “head-nodding” | “Central cyanosis” or SaO2 <90% | capillary refill >3 seconds | Conscious level (AVPU) < “A” | Pulse > 180 per min | Haemoglobin < 7g/dl | Blood glucose < 3mmol/L | white Blood cell count < 4 or > 17.5 x 109/L | Temperature <36 or >38.5oC | Eligible (Yes, No) | Enrolled (yes, No) | comments | staff Initials |
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1. **REFERENCES:**

* PB-SAM protocol

1. **DOCUMENT CHANGE HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version 1** | **Author** | **Approved by** | **Signature** | **Date** |
| 1.01 | Robert Bandsma/Isaiah Njagi | Wieger Voskuijl |  | **04-02-2021** |
|  |  |  |  |  |

**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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