# PURPOSE / INTRODUCTION:

* This SOP describes the procedures for enrolment of eligible participants who have consented to participate in the PB-SAM study according to study protocol.

# SCOPE / RESPONSIBILITY:

* This SOP applies to study clinicians, nurses and fieldworkers involved in enrolment of study participants.
* The Principal Investigator, through the lead clinician retains the overall responsibility on implementation of these standards and recruitment of suitable participants for the study.

# DEFINITIONS/ ABBREVIATIONS:

CRF- Case Report Form

SOP Standard Operating Procedure

ICH GCP- International Conference on Harmonisation (ICH) / WHO Good Clinical Practice standards

SAM Severe Acute Malnutrition

OPD Out Patient Department

# METHODOLOGY:

## 4.1 General consideration

* Study teams at the hospital should exercise due diligence to ensure that ONLY eligible participants and who have given informed consent are enrolled.
* Enrolment procedures will take place at the points of admission or in the Paediatric wards.

## Enrolment and documentation of trial participants

1. To enroll a participant into the PB-study, the patient must have been screened for eligibility (see Screening SOP) and given informed consent (See Informed Consent SOP). The enrolling clinician MUST make a final check of eligibility and informed consent before proceeding with enrolment. To enroll, 2 documents are required: Enrolment log and enrolment CRF.
2. Enrolment can occur at the time of admission or within 72 hours after admission in the ward. After a potential trial participant has been screened, confirmed eligible and consented to participate in the study, they will be randomised to receive the following study treatments.

Randomization 1:

1. Oral/enteral pancreatic enzymes: lipase, amylase and protease or
2. Oral/enteral matching placebo

Randomization 2:

* 1. Oral/enteral bile acids: ursodeoxycholic acid or
	2. Oral/enteral matching placebo
1. Each study site will be provided with sealed envelopes, labelled externally with study IDs, a randomization card with the allocation to pancreatic enzymes or placebo and allocation to bile acids or placebo.
2. Randomization of pancreatic enzymes/placebo shall be done by picking the envelope with the next sequential study number, as indicated on the randomization list.
3. When randomizing a participant, open the envelope and take out the randomization card and sticker in the envelope. The sticker that is inside will be stuck on the front page of the CRF.
4. Opening this envelope marks entry to the study and all subsequent events are ‘study events’. The randomization should be documented in the enrolment log.
5. If a randomization envelope is opened, a CRF must be filled even if the child withdraws or absconds.
6. Randomization to bile acids /placebo shall be done by picking the drug box for the study participant. The free label inside the drug box will also be stuck on the first page of the CRF.
7. A list with pre-defined study IDs will accompany the randomization envelopes. The CRF study number, the study ID from the Pancreatic enzymes/placebo randomization and the study ID from the bile acids/placebo randomization should match.
8. The admitting clinician will clerk the participant first using the hospital file and use the information to complete the CRF. The enrolment log must be filled in first before filling in the CRF (after ensuring that the child meets the enrolment criteria).
9. Research samples will be taken alongside routine admission blood samples taken (See blood collection SOP). A rectal swab and stool sample will be taken at enrolment, discharge, day 21 and day 60 (see rectal swab/stool collection SOP). The rectal swab which is less distressing to the patient should be taken first before taking the blood sample.

# APPENDICES

# Enrollment Log-PB-SAM Trial

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| --- | --- | --- | --- | --- | --- | --- |
| RANDOMIZATION NUMBER | SCREENING NO | DATEdd/mm/yyyy | SUBJECT INITIALS  | STUDY ID  | REMARKS | STAFF INITIALS  |
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# REFERENCES

1. PB-SAM Protocol
2. ICG GHP Guidelines

# DOCUMENT CHANGE HISTORY

This section is to be completed by the Quality Management or designee

**Version Table:**

|  |  |  |  |
| --- | --- | --- | --- |
| Version 1:Title:  **Anthropometry SOP** | Dated: **16/12/2020** | SOP No.:**04** | No. Pages: **8** |
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# SOP REVIEW AND UPDATING LOGS

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| DATE | NAME OF REVIEWER | SIGNATURE | REASON FOR REVIEW |
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**SOP 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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