



Study Specific Procedure			SSP No :003 Version No: 2.0 Supersedes:1.0 Effective Date:
Title: Randomisation and Labelling Procedure			
	NAME	SIGNATURE	DATE
PREPARER	Caroline Ogwang		
REVIEWING AUTHORITY	Moses Ngari		
Q.A. AUTHORITY	Aisha Bwika		
APPROVING AUTHORITY	Caroline Ogwang		

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1.0 PURPOSE / INTRODUCTION:

This SSP describes the standard procedures for the preparation of randomization envelopes and randomization drugs boxes for study participants of the FLACSAM trial in the 4 respective study sites.

2.0 SCOPE / RESPONSIBILITY:

2.1 This SSP applies to the FLACSAM study statistician, data manager, coordinator and other staff involved in the randomization of eligible study participants.

2.2 The Principal Investigator retains the overall responsibility for the implementation of this SSP.

3.0 DEFINITIONS / ABBREVIATIONS:

3.1 CRF: Case Report Form

3.2 FLACSAM: First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

3.3 SSP: Study Specific Procedure

4.0 MATERIALS

4.1 Randomization envelopes

4.2 Randomization cards

4.3 Randomization labels

4.4 Randomization list

5.0 METHODOLOGY:

5.1 Introduction

1. The FLACSAM trial will investigate two separate antimicrobial interventions in a 2x2 factorial design randomised controlled clinical trial. A factorial design allows more than one intervention to be tested and is useful in assessing a potential package of care.

2. Two randomizations will be made:

- Ceftriaxone/ Penicillin-gentamicin
- Metronidazole/Placebo

5.2 Procedures

1. Two independent randomisation lists will be generated using STATA with each using

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a different seed; one for Ceftriaxone/Penicillin-Gentamicin and the other for Metronidazole/Placebo. Each randomization list will have 2400 allocations with randomization done in random block sizes.

2. Envelopes will be used for the random allocation of ceftriaxone/penicillin-gentamicin while the metronidazole/placebo randomization will be implemented using labels stuck on drug boxes and bottles.
3. For ceftriaxone/penicillin-gentamicin randomization 3 labels will be generated:
 - A label that will be stuck on the outside of the envelope. This will have a unique study ID.
 - A label that will be stuck on the randomization card. This will have a unique study ID as well as the arm (Ceftriaxone or Penicillin & Gentamicin) to which the study participant has been allocated to.
 - An extra label that will be put in the envelope. This will be stuck on the first page of the CRF during enrolment.
4. Once the randomization lists have been generated, labels will be prepared separately for each arm of the two randomizations:
 - a) Labelling of randomization envelopes for Ceftriaxone/penicillin and Gentamicin
 - i. The study numbers for ceftriaxone will be separated from those of Penicillin and gentamicin.
 - ii. Labels with the study number and the allocation to Ceftriaxone will be printed and stuck to the envelope and randomization card at a different time from study numbers randomized to Penicillin-Gentamicin.

Example of a label to be stuck on an envelope

FLACSAM F0001

Example of a label for a study number randomized to ceftriaxone to be stuck on a card

F0001 Ceftriaxone

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- iii. Labels for study numbers randomized to Penicillin-Gentamicin will then be printed out and stuck to the envelopes and randomization card.

Example of a label to be stuck on an envelope

FLACSAM F0029

Example of a label to be stuck on a card for a study number randomized to Penicillin-gentamicin.

F0029 Penicillin & Gentamicin

- iv. Another label will be printed out with the study number and the randomization to which it applies (Ceftriaxone/Penicillin-Gentamicin, CPG) and will be put in the envelope to be later stuck on the CRF when the envelope is opened during enrolment.

Example of a label to be stuck on the CRF

F0005	CPG
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- v. Once the randomization envelopes for ceftriaxone and penicillin-gentamicin have been prepared, they will be put together and arranged sequentially.

b) Labelling of Metronidazole/Placebo Drug boxes-

- i. 3 labels will be used for every metronidazole/placebo drug box

- A label stuck on the drug bottle.
- A label stuck on the drug box

These two labels will have only the unique study ID.

- Another label will be placed within the drug box and will be stuck on the first page of the CRF.

This label will have the unique study ID as well as the randomization to which it applies. In this case the Met/Placebo randomization

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- ii. From the randomization list, study numbers allocated to metronidazole and placebo will be separated.
- iii. The labels will then be printed out and stuck to the bottles and drug boxes at different instances. Each randomization arm (Metronidazole or placebo) will have a day dedicated to it for sticking the labels on the drug bottles and drug boxes. This is to avoid mislabeling. The labels for the drug boxes for metronidazole/placebo will have the trial name and study ID

Example of a label for metronidazole/placebo to be stuck on the box

FLACSAM F0003

- iv. The labels that will be stick on the drug bottle will have only the study ID and will appear as below.

F0003

- v. Another label with the study ID and the randomization to which it applies (Met/Placebo) will be printed out and put in the drug box. This will be stuck on the first page of the CRF.

Example of the label to be stuck on the first page of the CRF.

F0003	Met/Placebo
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- vi. When the metronidazole drug boxes and the placebo drugs have been labelled, they will all be put together and arranged sequentially.
- c) Both the randomization envelopes and the drug boxes will be transported to site based on the study IDs allocated for each site.

6.0 APPENDICES: None

7.0 REFERENCES:

7.1 [FLACSAM](#) protocol

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8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: Randomization SOP	Dated: 13 July 2017	SSP No.: 003	No. Pages: 7
Version 2.0: Title: Randomization and Labelling SSP	Dated:	SSP No.: 003	No. Pages: 7
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE
20 th Nov 2019	Moses Ngari		<ul style="list-style-type: none">• Periodic SOP review• Adopted the SSP template.
20 th Nov 2019	Isaiah Njagi		<ul style="list-style-type: none">• Changed the approving authority to Caroline Ogwang from Greg Fegan as per QA advice.

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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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