



Study Specific Procedure			SSP No: 011 Version No: 2.0 Supersedes: 1.0 Effective Date:
Title: Sample Transportation SSP			
	NAME	SIGNATURE	DATE
REVIEWING AUTHORITY	Robert Musyimi		
QUALITY ASSURANCE AUTHORITY	Aisha Bwika		
APPROVING AUTHORITY	Caroline Ogwang		

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1.0 PURPOSE / INTRODUCTION:

The purpose of this SSP is to describe the standard procedures involved in transportation of study samples.

2.0 SCOPE / RESPONSIBILITY:

2.1 SSP is applicable to study clinicians, nurses, field workers and the sample courier personnel.

2.2 The principal investigator retains the overall responsibility for the implementation of this SSP.

3.0 DEFINITIONS

3.1 SSP: Standard Specific Procedure

3.2 SAM: Severe Acute Malnutrition

3.3 CRF: Case Record Form

3.4 CGMR-C: Centre for Geographic Medicine Research, Coast

3.5 CMR: Centre for Microbiology Research

3.6 CGH: Coast General Hospital

4.0 EQUIPMENT / MATERIALS

4.1 Cool boxes with ice packs

4.2 Sample storage vials

4.3 -80 degrees' Celsius freezer

4.4 -20 degrees Celsius freezer

4.5 Dry ice

4.6 Request forms

4.7 Sample register book

4.8 Transportation log

4.9 Sample reception register

5.0 METHODOLOGY:

5.1 General considerations

1. Study specimens to be transported include the plasma EDTA 1ml, plasma sodium heparin 1ml whole blood EDTA 0.5ml, plasma PK sample, blood culture samples whole stool and rectal swabs. The PK samples will be collected in (orange top) lithium heparin tubes.

2. 2 rectal swabs at admission, discharge day 45 and day 90 will be collected. One lab request form will be used for both rectal swab specimens. Whole stool will be collected at discharge and day 45
3. Inadequately packaged samples pose a health and safety risk due to leakage of contents, which may contaminate the staff, vehicles used for transportation, premises and sample reception facilities at the recipient laboratory. We should therefore ensure that samples are packaged appropriately.
4. All samples **MUST** be registered and logged onto the following registers/log forms
 - Sample register book: at the study site upon obtaining the sample
 - Transportation log: During transportation to the laboratory
 - Sample reception register at CGMRC Kilifi or CMR Nairobi
5. Personal protective equipment such as gloves and laboratory coats must be worn while handling microorganisms.
6. Blood Sample tubes must be transported in upright position to avoid spillage.

5.2 Procedures

5.2.1 Transporting PK samples

1. All PK samples will be transported to the respective labs immediately after collection to ensure that they are processed within 30 minutes.
2. The University of Washington Lab in Mombasa will receive PK blood samples for CGH. The PK samples will be processed and batched for shipment upon completion of the PK study to Kilifi. These samples will be stored in a -80 degrees' freezer.
3. Samples will be collected into heparinised tubes, centrifuged and the separated plasma stored at -80°C. Samples will be shipped in dry ice at the end of the study from the CGH to be securely stored at the KEMRI-CGMRC in Kilifi or at KEMRI-CMR in Nairobi then transferred to Strathmore University for analysis.
4. Prior to transporting the samples from the University of Washington lab at CGH (Mombasa) / Mbagathi laboratory to KEMRI-CGMRC in Kilifi or at KEMRI-CMR in Nairobi, the site study team must ensure that the laboratory staff at the recipient laboratory are aware that the samples are to be transported and are able to receive them upon arrival.

5. Ensure the tubes are tightly closed to prevent spillage and sample drying.
6. Samples will be transported in cooler boxes. The samples should be clearly labelled on the tubes with print freeze-proof labels and packed in card boxes with ice packs from the -80°C/ -20°C freezer.
7. A data file detailing all sample numbers should be sent along with the samples. Upon arrival, the recipient laboratory staff should compare the file with the IDs on the tubes initial and date the data file/ sample log and contact the site in case there are any differences.

5.2.2 Transporting rectal swabs

1. Rectal swab samples will be transported to the KEMRI, CGMRC, Microbiology Lab, Kilifi, KEMRI CMR Nairobi lab, Mbale Research lab in Uganda on a daily basis.
2. Rectal swabs will be stored in a 2-8°C refrigerator and must be transferred within 24 hours of collection to CGMRC Kilifi Microbiology lab or KEMRI CMR Nairobi lab for processing and archiving and Mbale Research lab for archiving only.
3. The rectal swab samples will be transported in cooler boxes with ice packs maintained at 2-8°C.
4. Ensure complete and clear labeling of the rectal swabs with accompanying appropriate laboratory requisitions for all specimen.

5.2.3 Blood culture samples

1. Blood culture bottles will be kept at room temperature but should be transferred to the laboratories at CGMRC Kilifi or CMR Nairobi for processing within 24 hours.
2. Ensure complete and clear labelling of the blood culture samples with accompanying appropriate laboratory requisitions for all specimens
3. Blood culture bottles will be transported in cool boxes without icepacks. Preferred temperature is room temperature.

5.2.4 Transporting whole stool

1. Whole stool samples will be transported to the KEMRI, CGMRC, Microbiology Lab, Kilifi, The University of Washington Lab in CGH Mombasa, KEMRI CMR Nairobi lab, KEMRI CGMRC and Mbale Research lab in Uganda on a daily basis.

2. Whole stool should be stored at -80°C freezer within 30 min after collection to CGMRC Kilifi Microbiology lab or KEMRI CMR Nairobi lab and Mbale Research lab for archiving only.
3. The stool samples will be transported in cooler boxes with ice packs maintained at 2-8°C immediately after collection to the designated labs.
4. Ensure complete and clear labelling of the stool with accompanying appropriate laboratory requisitions for all specimen.

5.2.5 Transporting whole blood samples (EDTA 0.5ml, Sodium heparin 1ml and EDTA 1ml)

1. All blood samples will be transported to the respective labs immediately after collection to ensure that they are processed within 30 minutes.
2. The University of Washington Lab in Mombasa will receive all blood samples for CGH. KEMRI CGMRC will receive all blood samples from KCH, KEMRI CMR will receive all blood samples from Mbagathi while Mbale Research lab will receive all EDTA blood samples from Mbale Hospital Uganda. The samples will be processed and batched for periodic shipment to Kilifi. These samples will be stored in a -80 degrees' freezer.
3. Samples will be collected into EDTA Purple top tubes and green top sodium heparin tubes. The EDTA and sodium heparin tubes will be centrifuged and the separated plasma stored at -80°C while the 0.5ml EDTA will be labelled using barcode and frozen.
4. Samples will be shipped in dry ice periodically from the all other sites to be securely stored at the KEMRI-CGMRC in Kilifi.
5. Prior to transporting the samples from any site to KEMRI-CGMRC in Kilifi, the site study team must ensure that the laboratory staff at the recipient laboratory are aware that the samples are to be transported and can receive them upon arrival.
6. Ensure the tubes are tightly closed to prevent spillage and sample drying.
7. Samples will be transported in cooler boxes. The samples should be clearly labelled on the tubes with print freeze-proof labels and packed in card boxes.

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- 8. A data file detailing all sample numbers should be sent along with the samples. Upon arrival, the recipient laboratory staff should compare the file with the IDs on the tubes initial and date the data file/ sample log and contact the site in case there are any differences.

6.0 APPENDICES

6.1 Sample Transport Log

SAMPLE TRANSPORT LOG

KEMRI/ WELLCOME TRUST LABORATORIES

FLACSAM STUDY

SAMPLE TRANSPORT LOG

POINT OF ORIGIN..... DATE (D D/MM/YYYY) /...../.....

DESTINATION..... DATE (DD/MM/YYYY)/.../.....

STUDY ID NO	LITHIUM HEPARIN	BLOOD CULTURE	RECTAL SWAB	EDTA 0.5ML	EDTA 2ML	STOOL	OTHER	COMMENTS

COURIER..... **DATE**..... **TIME**.....
RECEIVING **DATE**..... **TIME**.....
Temperatures at dispatch **Temperatures at Reception:**

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7.0 REFERENCES

FLACSAM Protocol

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: Sample Transportation SOP	Dated: 13th Jul 2017	SOP No.: 011	No. Pages: 7
Version 2.0: Sample transportation SSP Title:	Dated: 26th Nov 2019	SSP No.: 011	No. Pages: 8
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:

SOP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW
26/11/2019	Robert Musyimi		<ul style="list-style-type: none">• Periodic SOP review• Adopted the SSP template
26/11/2019	Isaiah Njagi		<ul style="list-style-type: none">• Removed Joseph Waichungo as the preparer of the 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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