Purpose

The purpose of this SOP is to describe the standard procedures involved in sample storage facility and management of the -80 ^{0}C freezers being used to ensure that the sample quality is maintained. It also provides a guide on emergency transfer of samples in case of power failure in the freezers used by CHAIN project to store samples. It also provides guidelines on proper logging of samples at site before shipment to the central processing and biorepository laboratory in Kilifi.

Responsibility

This SOP laboratory staff processing the samples and those that are responsible in maintaining the sample storage facility. It is the responsibility of the users to follow the guidelines stipulated herein.

The Principal Investigator (through the study coordinator when applicable) retains the overall responsibility of implementation of these standard procedures.

The Study Laboratory Coordinator is responsible for answering questions you may have about the content of this SOP and any other relevant study documentation. Please contact that the Study Laboratory Coordinator through your site coordinator.

Abbreviations/Definitions

SOP Standard Operating Procedure
PI Principal Investigator

Required material

- Power backup capacity
- Thermometers
- Cryoboxes
- Dry Ice
- Freezer Maintenance logs
- Back up freezers
- Back up lab
- Alarm systems
- Emergency contact list

Methods

1.0 General considerations

1.1 Freezer room temperature in which the CHAIN samples are being stored should be monitored and logged on temperature logs on a daily basis in the morning and evening. The freezer room should have air-cooling and ventilation installed to ensure that a room temperature of between 15°C - 30°C is maintained to prevent overheating of the equipment.
1.2 Freezer room airflow and humidity conditions shall be controlled by ensuring adequate air circulation around the freezers to avoid fungal growth. This will prevent excessive accumulation of moisture and condensation.
1.3 Cleaning of the facility should be done on a daily basis to avoid accumulation of dust in the facility.
1.4 Proper lighting should be provided to allow enough light to perform routine tasks in the freezer room.

2.0 General maintenance of the freezer

2.1 Ensure that the freezer doors for freezers where CHAIN samples are stored shall not be unnecessarily opened for more than 3 minutes to avoid temperature increases and only one rack or box may be removed at a time.
2.2 The CHAIN freezers should be inspected on a daily for cleanliness, malfunctions and possible temperature variation using freezer temperature logs.
2.3 Documented and maintain evidence of actions taken in case of any malfunctions and communicate with the laboratory network coordinator through your site coordinator.
2.4 Preventative maintenance of the freezers should be put in place at regular intervals as per manufacturer's recommendations.
2.5 Maintain temperature probe in the freezer to ensure that it captures accurate freezer temperature.
2.6 Test alarms for functionality of both temperature variation and electrical power supply interruption as regularly as possible and as stipulated in your SOP per your site SOP.
2.7 Ensure that all the freezers are numbered and that you have a functional 24-hour emergency contact list with a list of personnel to be contacted in case of freezer malfunction. The list should be reviewed on a regular basis to capture any changes of personnel contact or in case a staff has left your institution.
2.8 Train personnel on how to monitor and defrost mechanical freezers regularly and monitor daily for any frost build-up that may prevent proper sealing of freezer doors hence causing temperature fluctuations.

3.0 Backup Freezers or Facility

3.1 The CHAIN sample storage facility should have adequate backup of low temperature freezers to act as a backup in case of equipment failure that can accommodate the samples affected.
3.2 The facility should also be installed with a back-up generator with adequate reserve of fuel for up to 24 hours.
3.3 If you do not have a backup freezer available in your biorepository, if possible, make arrangements with a partner laboratory with a freezer facility to accommodate your samples

in case of a power failure.

4.0 Emergency Transfer of Samples

4.1 In case of failure of any freezer with CHAIN samples, document all the affected samples in a log and inform the CHAIN site coordinator immediately. Trained biorepository personnel should do rapid transfer of samples to the backup freezer.

4.2 The samples being transferred to the backup freezer should be documented to ensure return to correct location when corrective action has been taken.

4.3 All samples must be transferred in dry ice ensuring the least time possible is taken to transfer the samples and no temperature variation that may lead to thawing of the samples is attained. Any thawed samples should be documented and communicated to the lab manager.

4.4 A full report on what caused the freezer failure, complete inventory of the affected samples and the corrective action taken should be shared with the site PI/coordinator as well as the laboratory network coordinator.

5.0 CHAIN Sample Freezer inventory and shipping to central biorepository

5.1 All CHAIN samples and isolates should have a clear storage inventory on site so that these samples or isolates can be retrieved from their storage positions at a later date. During shipment, a clear inventory should accompany the samples with the following details captured i.e. Freezer name, Rack, Tray, Box number, date received, date frozen, row and column of where it is stored (Appendix 7.1).

5.2 The time and date of collection should be indicated as well as date and time of storage. All samples must be stored within 30 minutes of arrival in the laboratory.

5.3 Record all the samples on a shipping grid (Appendix 7.2) which should accompany the samples during shipment to the central processing and biorepository lab in Kilifi.

5.4 Ensure that you cross check that all the sample boxes have been packed and do a quality control check before sending the samples by randomly picking any 3 samples or isolates in the box and crosschecking with the inventory that they are stored in the correct position.

5.5 At all times, keep the samples in dry ice when sorting/preparing then for shipment.

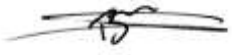
5.6 All the samples must be shipped in dry ice early in the week to ensure that they are received in Kilifi latest by Thursday to avoid samples arriving over the weekend.

4.0 CHAIN Sample shipment to the central biorepository

References

N/A

5.0 Document history

Version	Author	Approved by	Signature	Dated
1.02**CHAIN BIOREPOSITORY SOP (MASTER)**	Caroline Tigoi	Robert Bandsma		Jan 23 2021

6.0 Site training record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**
1.01	KDT	Example row	1st Jan 2016	DM

7.0 Appendices

7.1 Sample Shipment inventory log (List per box with 100 places)

Study Name	
Site Name	
Study No	
Freezer	
Rack	
Tray	
Box	
Tray_label	

serial_no	barcode	Sample_type	date_collect	date_recieved	date_frozen	vol	Col	Row
1							A	1
2							B	1
3							C	1
4							D	1
5							E	1
6							F	1
7							G	1
8							H	1
9							I	1
10							A	2
11							B	2
12							C	2
13							D	2
14							E	2
15							F	2
16							G	2
17							H	2
18							I	2
19							A	3
20							B	3
21							C	3
22							D	3
23							E	3
24							F	3
25							G	3
26							H	3
27							I	3
28							A	4

7.2 Sample shipment grid

CHAIN samples Box grid plan	A	B	C	D	E	F	G	H	I	J
1	Write Sample ID & date frozen here									
2										
3										
4										
5										
6										
7										
8										
9										
10										

SOP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SOP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SOP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
1.			
2.			
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