Standard Operating Procedure

SOP title	CHAIN SOP Management
Version	1.1
Date issued	26-02-2021

1. PURPOSE

This document describes the process by which CHAIN standard operating procedures (SOPs) will be written, approved, and updated over time.

2. INTENDED USERS

The intended user of this SOP is all individuals on the core CHAIN team and site teams who play roles in developing SOPs.

3. RESPONSIBILITIES

All CHAIN study staff should understand and follow this SOP. It is the responsibility of the site's Principal Investigator (PI) to ensure that all study staff comply with this SOP throughout the duration of CHAIN.

4. DEFINITIONS

4.1 **SOP:** A document that defines a research team's standard practices and approaches for addressing research objectives. The SOP ensures that all activities are aligned with relevant institutional guidelines while being harmonized across research sites.

5. REQUIRED MATERIALS

No required materials.

6. PROCEDURE

6.1. All SOPs should be structured with the following sections:

a. Purpose: Provide a short explanation for how and when this SOP will be used.
b. Intended Users: Describe the individuals for whom the SOP is relevant, such as field personnel, laboratory staff, site PIs, etc.
c. Responsibilities: Adapt the text above to ensure that it is clear that site PIs are responsible for ensuring that all SOPs are followed.
d. Definitions: Include definitions for any terms or procedures that are critical for understanding in order to proceed. Bold the name of the term. If no definitions are required, do not include this section.
e. Required Materials: List all materials that are required for carrying out the duties of the SOP. If no materials are required, write "No required materials".
f. Procedure: List the steps necessary for carrying out the SOP. Crucial steps can be

underlined or bolded.

g. Training Sheet: A table indicating the team(s) or individuals that have been trained on that SOP.

6.2. File naming convention:

a. All SOPs should have the following as a header:

Title v1.0 Logo
Standard Operating Procedure

b. The dated version number is added as a footer with a page number on the bottom right.
c. SOPs are filed under one of the following sections: -.
    i. Clinical SOPs
    ii. Laboratory SOPs
    iii. Data Management SOPs

Each site folder on Dropbox will have the above folders under their SOPs folder.

d. SOPs should be named starting with "CHAIN Title SOP" For example as in this case "*CHAIN SOP management SOP*"
e. A log with all SOPs with their status and versions will be kept and updated in a SOP control log.

6.3. Approval process

a. Master SOPs will be drafted by a designated individual on the CHAIN Co-ordination Team. This individual will add their name and the date to the document versioning box at the bottom of the SOP.
b. Each SOP draft will be reviewed by an individual on the CHAIN Co-ordination Team. This individual will add their name and the date to the document versioning box at the bottom of the SOP. If substantial edits are required, this individual should review the document again after the revisions are addressed by the original author.
c. After the SOP has been fully revised, the document will be reviewed by members of the CHAIN co-ordination or leadership and thereafter provided to the site PIs for adaptation, should any be required. See Section 6.4. for details.
d. After the adapted SOP has been approved by the site PI, the site PI will add their signature to the "Current Document Box" and email a signed copy of the SOP to the CHAIN Co-ordination team.
e. The CHAIN co-ordination team will review the adapted SOP and sign the final site-specific SOP in the "Current Document Box".
f. When SOPs are used during a training, trainees should sign the "training sheet" to indicate that they understand and will comply with the specific SOP. Sites should maintain copies of the "Training Log" for the duration of the study.

6.4. Adaptation at the local level

a. If a specific SOP requires adaptation at the local level, sites should use track changes to edit the document as necessary.
b. The edited version of the document will be sent to the CHAIN Co-ordination team in order to log changes across sites.
c. The CHAIN Co-ordination team will indicate that the adaptations are satisfactory and "accept" the adapted SOP, or communicate with the site team if there are any

questions/concerns.

6.5. Updating SOPs over time

a. Should any minor updates or changes to the SOP be required the initial author should make the change and the original SOP reviewer should be notified of the change. The revised SOP should be sent to the sites and the version number should be updated.
b. If any major changes or updates must be made to the SOP the initial author should make the change, the original SOP reviewer should be notified, and the CHAIN leadership should also be provided the SOP for review. The revised SOP should be sent to the sites and the version number should be updated.

6.6. Effective data

The effective date of an SOP is the date that the CHAIN leadership or Co-ordination lead signs the SOP. If the SOP is revised, the updated effective date should be updated in the Document History box at the end of the SOP.

7. References

7.1. Version control SOP
7.2. Electronic Filing SOP

8. Document history

Version 1	Author	Approved by	Dated	SOP No:
1.0	Narshion Ngao	Robert Bandsma	26-02-2021	

9. 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

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)
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