



Standard Operating Procedure

Commented [RB1]: I am assuming we will have one CHAIN filing SOP not one specifically for each trial

SOP title CHAIN Electronic Filing System SOP

1. Purpose

The following describes the protocol by which electronic documents are to be saved and stored at Co-ordination center in Nairobi and the University of Washington in Seattle. Files will be shared between the two sites using a program called 'DropBox'. All users will need to register for an individual Dropbox account in order to obtain access to the files. This will allow for restricted access where necessary.

Commented [RB2]: Change to onedrive?

2. Scope

This procedure is applicable to all CHAIN staff both in the coordination teams (Nairobi & Seattle) as well as those at sites. This is a File Management SOP. All members, including temporary staff, will be appropriately trained before executing this procedure independently.

3. Abbreviations/Definitions

- File – An electronic document that can be shared.

4. PERSONNEL/ROLE(S)

Study PIs/ Co-ordination team: Responsible for adhering to the naming procedure detailed below.

Gate keeper: Responsible for the implementation of the electronic filing system. All final versions of a file will be sent to the gate keeper. The gate keeper will ensure the document has been named appropriately. If not, he/she will return it to the author for appropriate naming based on guidelines below. The gate keeper will then update the index of 'Current Forms/Files' (discussed below) and sync using the dropbox program. They will also upload a latest version to the website and announce its immediate availability.

A member of co-ordination team from data management will be appointed as Gate keeper.

5. FILE STORAGE AND STRUCTURE

All files will be stored into a standardized file directory, organized by functional group on Dropbox.

Commented [RB3]: Or onedrive

Dropbox is used to share documents between the study leadership, coordination and site teams. There are three main folders on the Dropbox for sharing documents between these teams: -

- CHAIN – Contains subfolders for all sites and in every site folder there is: -
 - CRFs
 - PP Memos
 - Sample Transportation log
 - SOPs
 - Other site specific files.
- CHAIN_Coordination – Contains management documents for the coordination team. Has folders like: -

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- Data Management
- Lab Management
- Clinical Management
- Protocol
- Training materials
- Version Control
- E.t.c.
- CHAIN Leadership – Contains documents for the leadership team.

5. FILE NAMING

File names will all follow a standard format. All files names will contain these elements separated by underscores (_):

- Study initials – no more than 8 characters that will be consistent throughout the study
 - Examples: CHAIN, CHN_COST, CHN_BREAST etc.
- Document type/title
 - Example: Enrollment CRF, Follow-up CRF, Stool collection form
- Version Number
 - This will allow easier identification of most recent versions. Version number format is “v1.65”.

Therefore, an example for the study enrollment form is named as:
“CHAIN_Enrolment_v1.65”.

File names will be indicated on the bottom left of the document. Version number will be duplicated on the bottom right of the document.

Consent Forms:

A word version will reflect what was submitted for approval. This version will not be printed or edited without the PIs approval. Once approved, consent forms will be scanned into PDF format and saved with an additional file extension “_stamped” at the end of the file name. This version will be available to study staff to print. This will help prevent printing incorrect versions.

6. INDEXING

ALL FILES

Each study folder contains an ‘Index’ subfolder. As listed above in the personnel section, the gate keeper will be responsible to keep all indexes up to date. As current versions of a file become available, these will be reflected in an index document for the study.

Current example:

Form Name	Version date	Comments

In the future, even if similar forms are used in separate studies, they will have individual names to reduce confusion.

IRB RELATED FILES

For tracking and indexing of the IRB, a spreadsheet will be used to track approvals, modifications and amendments of the IRB. This file will be stored in the ‘Index’ sub-folder and will be called, “studyabbreviation_IRB_vdate.xls”



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An example of headers in this file is listed below
 “Study IRB Tracking Document”

Study	Institution/ Department	Document	Description	Submission Date	Disposition Date	Disposition	Notes	Renewal Deadline

7. References

8. Document history

Version 1	Author	Approved by	Dated	SOP No:
1.0	Narshion Ngao			

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	1 st Jan 2016	DM