



# Standard Operating Procedure

SOP title	CHAIN Version Control SOP
Version	1.0
Date issued	03-12-2018
Next Review	03-12-2019

## 1. Purpose

The purpose of this standard operating procedure (SOP) is to ensure that details of preparation and version control of study documents are accurately tracked and synchronized across the entire network.

## 2. Scope

Study documents that will be under version control include: -

1. Application code and scripts such as report dashboard app, data cleaning and reporting scripts.
2. SOPs, Policies and CRFs
3. Other important documents and diagrams e.g. Annual reports, environment diagrams, Sample collection charts, protocol procedures and workflows.

## 3. Abbreviations/Definitions

- Change – Any desired outcome expected to happen to an existing status quo item.
- Version – An identifier assigned to a document/file whose changes are under tracking.
- Git – a version control language that provides synchronization and tracking capabilities.
- GitHub – A version control repository hosted online that utilizes the git language. We shall be using a private repository for our CHAIN related scripts and code.
- Clone – A git command to create a copy of a repository mainly in a local computer
- Checkout – A git command to get all files of a repository branch to a local branch for working.
- Branch – An instance of a repository containing all files. Each branch may be evolve further on its own.
- Commit – A git command to effect changes to a working branch after making them.
- Set upstream/set track – A git command(s) to set remote branch where pull and push activities can be done.
- Pull – A git command to download latest changes from a remote branch to a local working branch.
- Push – A git command to upload changes that have been committed on a local branch to a remote branch.
- Pull request – A way of informing other collaborators to review and accept changes from a branch that has been evolved. Once the pull request has been approved, changed are merged to a common branch.
- Rebase - when a base of a local branch has changed, the local branch needs to be updated



- Minor Change - A change is considered minor if it does not introduce a different use case, functional application or meaning from the original context of the document. Minor changes are typically formatting and language re-wording.
- Major Change – A change is considered major if it provides a new approach, extends scope or provides more meaning and use cases of the document/file.

## 4. Requirements

The following resources will be needed in the implementation of this SOP: -

1. Version control log – An excel sheet to track version changes and document change logs.
2. GitHub Repository – A private repository to be hosted online for code and scripts tracking.

## 5. Responsibility

It is the responsibility of all study staff to understand and follow this SOP.

## 6. Procedure

### 6.1. Version Control Procedure for Study Documents

This procedure applies to study documents that are now under the GitHub version control repository. These include: -

- SOPs and Policy documents
- Case Report Forms (CRFs)
- Other important documents and diagrams e.g. Annual reports, environment diagrams, Sample collection charts, protocol procedures and workflows.

### Procedure

#### 6.1.1 Standardized identification of documents and definitions

- 6.1.1.1. *Document in draft:* Study documents that are in the development stage. They are neither approved by CHAIN leadership or relevant approval body nor have they been used to carry out study procedures and/or data collection.
- 6.1.1.2. *Final documents:* Study documents that are considered to be complete. They are neither approved by CHAIN leadership or relevant approval body nor have they been used to carry out procedures and/or data collection.
- 6.1.1.3. *Approved documents:* Study documents that are complete, approved and have a stamp of approval. Only approved documents are used for the collection of data and consenting of study participants.
- 6.1.1.4. *Version control:* Tracking all changes that have been made within a draft or final version of each individual document. Version control ensures that a correct version of any study document is being revised or used to carry out study procedures and/or data collection.
- 6.1.1.5. *Policy and Procedure Memorandum (PPM):* A numbered memorandum to inform the Study Staff and partners of changes to the study protocol; changes to the Manual of Operations; Study Forms and effective dates of change. The PPM is used to: announce suspension of enrollment or treatment protocol effective date; to clarify or interpret study definitions or items on the Study Forms; and announce any changes in the study staffs.

#### 6.1.2 Circulation of study documents in draft

- 6.1.2.1 Study documents are circulated among Study Staff for revisions and documents in the form of electronic files. All documents should be edited using track changes in Microsoft Word. As documents are edited, the document should be renamed with the same name but with an underscore and initials of the editor following the name. For example, if Chris Maronga



## CHAIN Version Control SOP v1.0

edits the document “CHAIN\_Enrollment\_CRF\_v1.65” he will rename it “CHAIN\_Enrollment\_CRF\_v1.65\_cm” which indicates that this is a track changed version of the v1.65 Enrollment form.

6.1.2.2 Staff involved in making revisions should communicate with each other regarding the changes made via meeting, emails, or conference calls, and work as a team in implementing them.

6.1.2.3 The person in charge of a given document will be responsible for accepting all track changes and will make a new clean version of a given document with the new name corresponding to the new date. For example a document may go from the original, “CHAIN\_Enrollment\_CRF\_ v1.65”, through two reviewers, “CHAIN\_Enrollment\_CRF\_ v1.65\_cm” and “CHAIN\_Enrollment\_CRF\_ v1.65\_cm\_nn” and then be finalized by CM with the name “CHAIN\_Enrollment\_CRF\_ v1.66” for a minor change or CHAIN\_Enrollment\_CRF\_ v2.0 if implementing a major change.

### 6.1.3 Version control and file naming:

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

6.1.3.2 Study name, CHAIN, will be consistent throughout the study

6.1.3.3 Document type/title

- Example: Enrollment form, Follow-up form, Stool collection form
  - Version Number
    - Version number will be used for all the case report forms (CRFs), logs and standard operating procedures (SOPs) and other formal study documents. Once a CRF or SOP has been updated, the version number will change to the next digit for example from version 1 to 2. This will be logged in the Document Version History Log which tracks the date of change, effective date, version and description of change. The document will be uploaded in Website as the latest version to be used at all sites and all previous versions of that form will be removed from Website to an offline archive.
    - If versions are edited multiple times in one day, the current version number will be used until the document is finalized on and finally moved to the next version whole number.
    - The document version will be indicated on the bottom left of the document (version 2.0).

6.1.3.4 The top left corner (header) should contain the name of the document (excluding date) preceded by the name of the study “CHAIN” for example.

6.1.3.5 For SOPs, when a version is updated, the version history at the end of the SOP needs to be updated. This will be done annually and all SOPs will be reviewed. If no change is made on the SOP, the annual review signature table will be completed.

### Dropbox

6.1.3.6 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: -
    - Data Management
    - Lab Management
    - Clinical Management
    - Protocol
    - Training materials
    - Version Control
    - E.t.c.
  - CHAIN Leadership – Contains documents for the leadership team.
- 6.1.3.7 CRF and SOP folders in dropbox will be organized by version (i.e. 1.0, 2.0) etc. and within each version folder is a “Track Changes” folder where the track changed version(s) of the document is stored. The latest version of any document will also be placed in a separate folder named “Final Version” which will contain the most recent version of each study document. For example, there may be SOPs that are still in their first version and some that have gone through multiple changes and are now at version 3.0. Therefore the Final Version folder will contain the most recent (whether it be version 1.0 or version 3.0) of the SOP.
- 6.1.3.8 The Ethical approval folder in dropbox is organized by regulatory authority first (UW/KEMRI/PPB) and then within each folder, by submission and approval organized numerically. For example a modification submitted on 21Mar2016 would appear in the folder starting with it’s chronological number and the date it was submitted, i.e. “10. Modification #3\_21Mar2016”. When approved, the approval documents will appear in a separate folder, assigned the next number and indicated approved, i.e. “Modification #3\_Aproved\_29Mar2016”.

**NOTE:** Study documentation to be used for the enrolment sites should never be retrieved from the dropbox folders because these folders contain draft and intermediate versions of documents. The CHAIN website is the sole source of documents to be used at the sites.

### CHAIN Website

- 6.1.3.9 All final documents to be used at study sites are stored on the CHAIN website in the following location: <http://chainnetwork.org/resources/> . The site staff only needs to download documents from this folder.
- 6.1.3.10 When a study document is updated, the new version is sent to the Website Administrator along with the updated Document Version History. The web admin will upload the documents into the FORMS IN USE AT SITE folder and will move the old versions to offline.
- 6.1.3.11 The documents in the FORMS IN USE AT SITE folder will be duplicated in the other folders as well (i.e. the Consents Folder will also contain the same version of consents) and this duplication is to maintain organization structure for those of us keeping track of all study related documents. However, for the purpose of documents at the site, the study team is to only refer to the FORMS IN USE AT SITE folder.

### 6.2 Version Control Procedure for GitHub controlled sources

This procedure applies to source code files that are versioned under the GitHub system. These includes: -

- Data Curation Group scripts – For the scripts that do extraction, cleaning and releasing of datasets.
- CHAIN Report Dashboard code and scripts – The code that publishes reports on the dashboard.

## CHAIN Version Control SOP v1.0



- Website code
- TGHN report on “We are CHAIN” tab.
- Annual report data summaries report code

### Procedure

- 6.2.1 Ensure you have an account on Github.com. Access the CHAIN repository page on: [https://github.com/KEMRI-WellcomeTrust/CHAIN\\_Network](https://github.com/KEMRI-WellcomeTrust/CHAIN_Network)
- 6.2.2 Install github client for your operating system. Check this page for reference on what you need to install: <https://git-scm.com/downloads>
- 6.2.3 Once you are done installing git, you should see “Git Bash Here” on the context menu when you right click on a folder. On your computer, navigate to a folder (or create a new one) where you want to save your local working copy of the repository to wish to work on. Right click on the folder then select Git Bash Here. This opens a command line interface window.
- 6.2.4 To download a copy of the repository, from the github.com page of the repository, click on “Clone or Download” button on the main page of the repo. Click on the button next to the URL to copy the link to your clipboard.
- 6.2.5 Go to the Git command line interface and clone the repository using this command:  
Git clone <URL>  
This will clone the Master branch to your local computer.
- 6.2.6 Checkout a working branch to your private repo. At the time of writing this, the remote working branch is 1.0-dev. Contact the data team for advice if you are not sure.  
Git checkout <working branch>
- 6.2.7 Create a local branch of the working branch you checked out. (-b)  
Use: git checkout -b <workingbranchname>
- 6.2.8 Work locally on your code. Make changes on your files.
- 6.2.9 Commit the changes on your local. Using Git add then git commit  
Git add \* (notice the asterisk is used for adding all changed files. Otherwise specify the path of the file for specific files).  
Git commit -m “your commit message”  
You can also do both steps with: Git commit -a \* -m “your commit message”
- 6.2.10 Link your local branch to a remote base using: Set upstream/set track. E.g.  
Git -set-upstream origin <remote branch>
- 6.2.11 Push the branch to remote branch using git push command.
- 6.2.12 Go to Github.com repository and create a pull request.
- 6.2.13 At least 2 people have to approve your pull request.
- 6.2.14 Once approved, other people can now update their working copies using git pull.

## 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.

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