**STUDY DOCUMENT PREPARATION, USE, AND VERSION CONTROL**

1. **PURPOSE**

This SOP provides details of preparation and version control of study documents. Preparation of study documents is a complicated process. The following are used to ensure accurate tracking of versions:

* Version control of each individual study document
* Structured flow of study documents among team members who are involved in the preparation of documents
* Structured revision process of final documents that are already in use

1. **RESPONSIBILITIES**

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

1. **REQUIREMENTS**
   1. Tracking Logs
2. **PROCEDURES**
   1. **Standardized identification of documents and definitions**
      1. *Document in draft:* Study documents that are in the development stage. They are neither approved by IRB/ERC approval nor have they been used to carry out study procedures and/or data collection.
      2. *Final documents:* Study documents that are considered to be complete. They are neither approved by IRB/ERC nor have they been used to carry out procedures and/or data collection.
      3. *Approved documents:* Study documents that are complete and approved by both IRB/ERCs and have a stamp of approval. Only approved documents are used for the collection of data and consenting of study participants.
      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.
      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.
   2. **Circulation of study documents in draft**
      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 Patty Pavlinac edits the document “TotoBora\_Enrollment\_22Feb2016” she will rename it “TotoBora\_Enrollment\_22Feb2016\_pp” which indicates that this is a track changed version of the 22Feb2016 Enrollment form.
      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.
      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, “TotoBora\_Enrollment\_22Feb2016”, through two reviewers, “TotoBora\_Enrollment\_22Feb2016\_pp” and “TotoBora\_Enrollment\_22Feb2016\_pp\_cm” and then be finalized by PP with the name ““TotoBora\_Enrollment\_14Jun2016”.
   3. **Version control and file naming:**
      1. File names will all follow a standard format. All files names will contain these elements separated by underscores (\_):
         1. Study name, TotoBora, will be consistent throughout the study
         2. Document type/title

* Example: Enrollment form, Follow-up form, Stool collection form
  + Version Date
    - Version date will be used for the protocol and the consent forms and this will replace version number. This will allow easier identification of most recent versions. Version date format is “DayMonthYear”. For example – 22 Feb 2016 is “22Feb2016”. We will use 3 letter month abbreviations. For single digit days, include a 0 before the day. For example – 3 May 2016 is “03May2016”.

If versions are edited multiple times in one day, continue to use the version date for that day.

* + - * + Version Number

Version number will be used for all the case report forms (CRFs), logs and standard operating procedures (SOPs). Once a CRF or SOP has been updated, the version number will change to the next digit for example from version 1 to 2. The Seattle based staff in charge of study documents will communicate with the Study Coordinator to identify the start date for the form. This will be logged in the CRF Version History Log which tracks the date of change, effective date, version and description of change. The document will be uploaded in SugarSync as the latest version to be used at the site and all previous versions of that form will be removed from SugarSync.

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).

* + - 1. The top left corner (header) should contain the name of the document (excluding date) preceded by the name of the trial “University of Washington/KEMRI: Toto Bora Trial” for example.
      2. 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**

* + 1. Dropbox is used to share documents between the study leadership team. The Toto Bora trial has a unique folder in Dropbox within which there are multiple sub-folders devoted to SOPs, CRFs, Ethical Approvals, etc.
    2. 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.
    3. 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\_Approved\_29Mar2016”.
    4. **NOTE:** Study documentation to be used for the enrollment sites should never be retrieved from the dropbox folders because these folders contain draft and intermediate versions of documents. Sugarsync is the sole source of documents to be used at the sites.

**SugarSync**

* + 1. All final documents to be used at study sites are stored on SugarSync in the following location: Co-infections | (Toto Bora) “AZM” | FORMS IN USE AT SITE. The site staff only needs to download documents from this folder.
    2. The FORMS IN USE AT SITE folder contains the most up-to-date versions of the following documents:
       - Consents (in a “Consent” sub-folder)
       - CRFs
       - SOPs (in a “SOP” sub-folder)
       - KEMRI Protocol
       - Document Version History Table (in an “Index” sub-folder)
       - Old Forms (contained within an “Old Form” sub-folder)
    3. The Document Version History Table contains the exact file name of all study documents to be used at site, along with the name of the previous version of the documents so it is clear when a document has been replaced by a more current version.
    4. When a study document is updated, the new version is sent to the SugarSync Gatekeeper along with the updated Document Version History. The Gatekeeper will upload the documents into the FORMS IN USE AT SITE folder and will move the old versions to the Old Forms sub-folder.
    5. 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.

1. **APPENDIX 6 *(see below)***
   1. Training Documentation Log

**APPENDIX 6**



**KEMRI/UNIVERSITY OF WASHINGTON**

**P.O BOX 2651-00202 Nairobi, Kenya**

**Training Documentation Log**

**List of Individual trained on specific topic**

SITE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DATE ­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Description of Training:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FACILITATOR:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FACILITATOR:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Name** | **Title** | **Signature** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

\**The employee signature indicates that I have reviewed the indicated SOPs or attended the outlined training and understands their content and sought clarification if necessary*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Current Document** | | | | |
| **Version No.:** | 3.0 | | | |
| **Developed by:** | Patricia Pavlinac | | **Date:** | 11May2017 |
| **Reviewed by:** | Christine McGrath | | **Date:** | 12May2017 |
| **Effective Date:** | 12Jun2017 | | | |
| **Approvals**  *I have reviewed and approve this SOP for implementation.*  Dr. Benson Singa 13May2017 | | | | |
| **Principal Investigator** | | **Signature** | | **Date** |

|  |  |  |
| --- | --- | --- |
| **Document History** | | |
| **Version No.** | **Effective Date** | **Brief description of change** |
| 1.0 | 18Jan2016 | * Original |
| 2.0 | 20May2016 | * Edits made before study initiation and was not tracked |
| 3.0 | 12Jun2017 | * Addded version number in 4.3.1.2 and SOP annual review in 4.3.1.4 * Minor edits for clarity |
|  |  |  |
| **Document COPY Control** | | |
| **SOP Distribution for: Study Document Versioning SOP** | | |
| Original | Nairobi Office (Central TMF-SOP File) | |
| Copy | Homabay Office (TMF- SOP File) | |
|  | Homabay Enrollment Room | |
|  | Homabay Lab (SOP File) | |
|  | Kisii Office (TMF-SOP File) | |
|  | Kisii Enrollment Room | |
|  | Kisii Lab (SOP File) | |
|  | CMR Lab (SOP File) | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Annual Reviewers Table. To be completed when no changes are required.** | | | | |
| **Date** | **Author/ Designee** | **Reviewer** | **Principle Investigator** | **Comments** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |



**KEMRI/UNIVERSITY OF WASHINGTON**

**P.O BOX 2651-00202 Nairobi, Kenya**  
**Read and Review Log**

**List of Individuals who read and reviewed the SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Name** | **Title** | **Signature** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

\*By signing this log, participants confirm that they have read and understood the content of the SOP