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| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Archiving Essential Documents SOP** |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

**12.1 Purpose**

To describe the procedure of archiving essential documents during the entire course of the study and also to document the method to archive the essential document at [INSTITUTION] for the required period of time.

**12.2 Scope**

This SOP will apply to all clinical trials conducted at [INSTITUTION].

**12.3 Procedure**

Essential Documents are those documents which individually and collectively allow the evaluation of the conduct of a study and the quality of the data generated. These documents demonstrate the compliance of the Investigator, Sponsor and Monitor with the Good Clinical Practice and with other applicable regulatory requirements.

Essential Documents are needed for Sponsor’s independent audit function and inspection by the Regulatory Authority.

The Principal Investigator is responsible for archiving essential documents at the respective sites in accordance with the requirements of the Sponsor (or CI if appropriate), the institution and local requirements.

The Investigator should maintain documents as specified in the essential documents’ list (AX1-V3/SOP 12/V3) and take measures to prevent accidental or premature destruction.

Filing space should be available for the storage of Trial Master File (TMF) during the conduct of the clinical trial. Investigator site files will normally be stored at PIs office or local secure filing area. At the end of the trial the files must be transferred to PI specified site archiving facility.

The various Essential Documents needed for different stages of the study are classified under three groups:

* Essential documents before the clinical phase of the study commences (see 12.3.1)
* Essential documents during the clinical conduct of the study (see 12.3.2)
* Essential documents after completion or termination of the study (see 12.3.3)

**12.3.1 Archival of essential documents before the clinical phase of the study commences**

Before the study initiation visit, the CTC will create, or be given by the Sponsor/Contract Research Organization (CRO), a ring binder in which all required regulatory documents, forms and correspondence will be kept. If the Sponsor/CRO requires additional forms, or documents, these will be maintained in addition to the documents listed in AX2-V3/SOP12/V3.

The CTC will ensure that the appropriate documents are placed in the TMF on a regular basis. The CTC will make the file available for review by the Monitor at each site visit.

**12.3.2 Archival of essential documents during the clinical conduct of the study**

Signed informed consents must be stored in a separate file/binder which should be named “Signed Informed Consent Form” and mention PI name, study number and title on the binder.

If the Sponsor/CRO has given no specific direction concerning storage of informed consents in the TMF, then they must be stored as specified by the Sponsor/CRO.

Original source documents (case file) will be kept at the PI’s department during the study. A copy of the source documents (case file) will be created once study is completed and the original source documents (case file) will be stored in the hospital medical record. Contracts such as the Confidentiality Agreement, Investigator Agreement, and Publication Policy Agreement can be stored separately in the investigators offices of Company (i.e., not with the study records).

All communications with IRB, Sponsor/CRO and the documents received from the sponsor/CRO (e.g. News Letters, Central Lab information’s, etc) will be stored in a timely manner in the file/binder.

Subject reimbursements document will be stored in separate file/binder.

A separate file/binder for each subject can be prepared if required by the investigator for filing any extra documents like printout of the screen shot of the web screening and randomization confirmation, drug dispensing record, etc.

The CTC or delegate will transcribe the appropriate data from the source documents into each subject’s Case Report Form (CRF).

The CTC will ensure that the CRFs are stored in a secure location (i.e., Monitors should not have access to another study documents).

All site-related materials should be made available for review by the sponsor's representatives (monitors and auditors) or regulatory authority(s).

**12.3.3 Archival of essential documents after completion or termination of the study**

Essential documents need to be archived once the trial is completed e.g. the trial has undergone a final closeout visit (refer SOPs of close out visit in IEC communication Interaction with sponsor.)

During the final closeout visit monitor along with the PI and the CTC must identify the study specific documents that require to be archived.

The documents identified must be inventoried, packed in archival boxes, sealed and boxes must be labeled appropriately to indicate the tenure of archival, the content of the box and the study reference number (AX3-V3/SOP 12/V3).

*(Note: Xerox copy of the subject source will be stored in the archiving boxes.)*

The PI must assign an area to store the sealed archival boxes with restricted access.

The documents should be archived in an appropriate room or locked cupboard (consider fire protection without water sprinkler systems, water protection, for humid conditions, pests etc). The room or cupboard must be secure with access only by authorized personnel.

Documents must be stored in a way that preserves their integrity and readability and restricts access to appropriate individuals only.

Upon request of the Sponsor, Monitor, Auditor, IEC, or Regulatory Authority, the Investigator should make available all requested trial-related records.

PI/CTC must record and retain the inventory AX4-V3/SOP\_12/V3– Archive Inventory) record for future reference.

The study documents must be archived for 15 years post the study close out or until the sponsor confirms that the records are no longer required; whichever is earlier. However; prior to destroying the records, a confirmation for destruction of records must be sought by the PI from sponsor.

In case there is not enough space for storage of the study records in TMH, then the PI can place the study record in a secure off-site facility i.e. in ACTREC where they may be readily accessed in the event of an audit.

If the Principal Investigator leaves the organisation, he/she will provide the Sponsor/CRO with written notice of the location of the study records and the name and phone number of an alternate contact in the event of an audit.

**12.4 Applicable Staff**

This SOP applies to all the personals of the clinical research team who may be responsible archival of essential documents at [INSTITUTION].

These include the following:

* Investigator
* Research Team (listed in the delegation log)
* CRC

**12.5 Staff responsible for Implementation**

The research dept will ensure that the research team involved in the conduct of the study will comply with this site SOP.

The research dept and PI at will ensure that, at the time of implementation of the SOP, that the research team at [INSTITUTION] are trained and in the event that an SOP is modified, provide training regarding the change(s) and ensure their compliance with the changes.

Inform IEC that this site SOP will be implemented within the institution.

**References**

1. 21 CFR 312.55 – Informing Investigators

2. 21 CFR 312.57 – Record Keeping and Record Retention

3. 21 CFR 312.58 – Inspection of Sponsor Records and Reports

4. 21 CFR 312.62 – Investigator Record Keeping and Record Retention

5. 21 CFR 312.64 – Investigator Reports

6. Appendix V-CDSCO guideline: Essential Documents

7. ICH Guidelines for Good Clinical Practice (E6) section 4.4 – Communication with IRB/IEC

8. ICH Guidelines for Good Clinical Practice (E6) section 4.9 – Records and Reports

9. ICH Guidelines for Good Clinical Practice (E6) section 5.22 – Clinical Trial/Study Reports