Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Category: Study conduct

Title: Archiving documents

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Table of Contents

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1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for storing inactive study files and administrative documents in a secured manner while maintaining access for review by auditors and inspectors.

2. Scope

This SOP applies to archiving the study related documents for the time period required as well as to retrieve these files as needed.

3. Responsibilities:

Head of the Department (HoD), Study Coordinator and the Secretary to the HoD will be responsible for maintaining inactive study related documents.

4. Applicable rules, regulations and guidelines

- New Drugs and Clinical Trials Rules, 2019
  https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants ICMR, 2017
  https://www.indiascienceandtechnology.gov.in/sites/default/files/file-uploads/guidelineregulations/1527507675_ICMR_Ethical_Guidelines_2017.pdf

- International Conference on Harmonization, Guidance on Good Clinical Practice ICH GCP E6 (R3)
  https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)

5. Reference to other applicable SOPs

SOP No: D 12/07 Source documents.

SOP No: D 16/07 Establishing a Trial Master File (TMF)

6. Detailed instructions

6.1 Procedure for archiving the documents.

6.1.1 After the submission of the clinical study report (CSR) for academic and sponsored studies to the IEC, or after the completion of the study (awaiting CSR from sponsor), as per instructions from the PI, the procedure for archiving the study documents must be initiated.

6.1.2 All the files pertaining to the study including the participant files, electronic data in the form of compact disks and trial master files must be archived.

6.1.3 Archiving of study files must be done by the study coordinator under the supervision of the PI and HoD.

6.1.4 At the time of archiving, the study coordinator must enter the details of the study in the archival ledger present in the archival room of ward 24, 2nd floor, New M.S. building, K.E.M. hospital and specify the location of the study file in the index.

6.1.5 The index of the archival ledger shall list the study files numerically by study number. Each entry on the index shall list the study number, the date the study file was archived, and the title of the study.

6.1.6 Archived study files shall consist of:

- Trial master files including for example, the protocol and Informed consent document (ICD) versions, interim reports, all correspondence (with sponsors, ethics committee etc.) and a master copy of the final report.
- Patient related documents [including all source documents, Case Record Forms (CRFs), filled Informed Consent Forms (ICFs)]
- Any other relevant documents
- An electronic copy of the final report [if requested by the sponsor]

6.1.7 The archival of each study will be done with a third-party organization (for e.g. IRON MOUNTAIN), for which a sum of Rs 50,000 per year will be taken by the institute from

the sponsor (in case of regulatory studies)/funder for an archival period of one year. This sum shall be included at the time of initial budgeting of the study.

6.1.8 The sponsor/funder has to pay the total archival amount to the principal investigator and institute which will be calculated based on the number of years of archival required by them (50,000/year). This payment has to be paid by the sponsor/funder by the end of the study or with the last invoice to the PI.

6.1.9 The site principal investigator will archive any study for a minimum of 5 years and a maximum duration of 10 years and not more. The sponsor/funder shall take the responsibility for archival of the study beyond 10 years.

6.2 Accessibility of archived documents

6.2.1 The key(s) of the archival room will be available only with the HoD.

6.2.2 The HoD or the designee shall be the only individual with access to the archives. The HoD will designate an alternate person when he/she is absent. In the event of the retirement of the HoD, the key(s) to the archives will be passed on to the subsequent HoD who will assume the responsibility for archiving.

6.2.3 A check-in/check-out log for the archived document will be kept by the secretary to the HoD. This log shall contain the following information:

- The study number and Title of the study
- The name of the borrower
- The check-in date.
- The check-out date.
- Spaces for the secretariat and borrower to initial both the check-in and check-out date

6.3 Retrieval of already archived documents.

6.3.1 Requests for retrieval of already archived documents by sponsor(s) should be made to the HoD.

6.3.2 A separate ledger called 'Archives retrieval ledger' kept in archival room of the department must be maintained for study files which are accessed after archival.

6.3.3 During every retrieval, an entry should be made in the ledger by the study coordinator stating the name of the person seeking retrieval, date, and purpose of retrieval.

6.3.4 No alterations or additions shall be made to those files.

6.3.5 The study file(s) shall be returned to the study coordinator by the same individual who retrieved it in the same organized manner as it was retrieved earlier.

6.3.6 During return of the retrieved files, the study coordinator and the borrower should initial in the archival retrieval ledger.

6.3.7 Overall supervision of the procedures will be done by the respective PI of the study.

7. Abbreviations:

i.	CRF	: Case Record Form
ii.	CSR	: Clinical Study Report
iii.	GCP	: Good Clinical Practice
iv.	HoD	: Head of the Department
v.	ICD	: Informed Consent Document
vi.	ICF	: Informed Consent Form
vii.	ICH	: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
viii.	ICMR	: Indian Council of Medical Research
ix.	IEC	: Institutional Ethics Committee
x.	PI	: Principal investigator
xi.	SOP	: Standard Operating Procedure
xii.	TMF	: Trial Master File

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