


SOP 18	 <p style="text-align: center;">Sri MANAKULA VINAYAGAR Medical college and Hospital</p>	
SOP code: SOP 18/ V4	Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents	Effective Date: 02.01.2024

Title: Maintenance of active study files, Administrative records of the ethics committee, Archival of closed files and retrieval of documents

1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Ethics Committee (EC), EC administrative documents, archival of closed files and retrieval of documents.

2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and EC administrative documents by the EC Secretariat.


3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and EC records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

4. Detailed instructions

4.1. Maintenance of the Active Study Files

- A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the EC office.
- All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of
 - All original research proposal documents (including Covering letter, checklist of submission, EC application form, research proposal, data collection formats, case report forms, investigators brochures, informed consent documents etc) reviewed and approved
 - Reviewer's assessment forms
 - Decision letters (intimation letters) sent to the investigators
 - Study approval letter

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- Amendments and any other correspondence
- Study progress reports and interim reports
- Serious adverse event (SAE) report forms submitted by investigators
- Other record related to SAE, medical management and of trial participants and compensation paid
- Recommendations given by Ethics Committee for determination of compensation
- Records related to any order issued for premature termination of study with a summary of reasons thereof
- Final report of the study including microfilms, compact disks or video recordings
- Any other reports
- EC correspondances

- Strict confidentiality will be maintained for the contents of the files
- All active files will be kept secured in a file cabinet with controlled access.
- A log book for accessing the files by authorized staff & members will be maintained.

4.2. Maintenance of the EC Administrative Records

The EC records will include the following:

1. Constitution of EC (Authority letter)
2. EC members' records
 - i. Appointment and acceptance letters of each member
 - ii. Signed and dated confidentiality agreements
 - iii. Updated Curriculum vitae (hard copy or soft copy)
 - iv. Training records for each EC member (GCP, SOP)
 - v. Documentation of resignations / terminations
3. EC membership roster - An EC roster will be maintained which will contain:
 - i. Names of EC members
 - ii. Age
 - iii. Gender
 - iv. Evidence of qualifications
 - v. Role on the EC
 - vi. Status of affiliation to institution (e.g., unaffiliated or affiliated)
 - vii. Regular/ Alternate member to the EC (if applicable)

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4. EC mandate
5. Correspondence related to changes in EC membership with DCGI, OHRP or any other concerned authority
6. EC attendance roster
6. Agenda and Minutes of EC meetings with signature of Chairman
7. Standard operating procedures (SOPs) of EC
8. Annual reports
9. Documents related to Workshops & conferences organized by EC (Continuing education for members & staff)
10. SOP training and distribution logs
11. National and International guidelines followed by EC

4.3. Maintenance of Closed Study Files


- Once the study file is closed (following completion/ premature termination), the related study files will be shifted to the EC Archival room.
- All closed study files will be archived in the EC archival room for a period of five years from the date of closure of the study.
- A log book for archival of study documents will be maintained.

4.4. Accessibility / Retrieval

- Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on SAEs) on request (*AX 01/ SOP 18/V4*) if authorized by Member Secretary/ Chairman.
- Representatives of regulatory authorities may have access at all times.
- A log book of retrieval of documents will be maintained.

4.5. Disposal of Closed Files and Copies of Protocols and Documents Submitted for EC Review

- At the end of the archival period, the closed files will be shredded and disposed of by authorized EC personnel.

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- Extra copies of protocols and documents submitted for EC review and any other extra copies will be shredded by authorized EC personnel after the EC meeting without any notification to PI.
- A formal disposal log will be maintained, providing details of documents that will be disposed. (AX 02/ SOP 18/V4)

5. Reference to other applicable SOP: NIL

6. Annexures


Annexure 1 AX/01/SOP 18/V4 Document Request Form

Annexure 2 AX/02/SOP 18/V4 Log for disposal of study documents

Annexure 1: AX 01/ SOP 18/V4

Document Request Form

Project No.:	
Project Title:	
Name of Principal Investigator (PI):	
Requested by:	
Documents requested:	
Purpose of the Request	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary / Chairman with date:	

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Annexure 2: AX 02/SOP 18/V4

Log for disposal of study documents

Project No.	Title	Name of Principal Investigator	No. of files	Date of EC Approval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

7. Flowchart

No.	Activity	Responsibility
1	Organize the contents of the active study files	EC Secretariat
2	Maintain the active study files and Administrative Documents	EC Secretariat
3	Archival of Study files	EC Secretariat
4.	Authorising retrieval of archived Documents	EC Member secretary/ Chairman
5.	Disposing closed study files and maintaining Document disposal log	EC Secretariat

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8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: <http://www.ferci.org/sops/>
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

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