18.1. Purpose

To provide instructions for preparation and maintenance of active study files and other related approved documents, IEC administrative documents, archival of closed files and retrieval of documents.

18.2. Scope

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

18.3. Responsibility

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

18.4. Detailed instructions

18.4.1. Record/database of new proposals

● The IEC secretariat will maintain written and electronic records of each application received in the following manner:

1. Assign unique project identification number
2. Name of the PI(s) and Co-Is
3. Name of the responsible institution or organisation
4. Title of the project
5. Date of review in IEC meeting and the decision(s) taken at this meeting
6. Decision of IEC with date
7. Approval or non-approval of any changes to the project
8. Suggestions, if any, of approval of the project and
9. Type of approval, whether by expedited or full committee review.

18.4.2 Maintenance of the Active Study Files

- A study master file is prepared 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 IEC 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 proposals reviewed and approved,

- Reviewer's assessment forms

- Agenda of IEC meetings

- Minutes of the IEC meeting

- Study approval letter

- Reviewed and approved consent documents,

- Amendments and any other correspondence

- Study progress reports and interim reports,

- Serious adverse event report forms submitted by investigators,

- DSMB and monitoring reports

- Any other reports

- IEC correspondence

Note:

• 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.

18.4.3. Maintenance of the IEC Administrative Records

The IEC records will include the following:

18.4.3.1. IEC members' records

i.   Appointment letter with terms of reference regarding term of appointment , role in IEC and acceptance letters/emails or other evidence of each member with sign and date

ii.   Signed and dated confidentiality and COI agreements

iii.   Updated Curriculum vitae (hard copy or soft copy) with sign and date and   evidence of qualifications.

iv.   Training records for each IEC member (Human protection, GCP, SOP)

v.   Documentation of resignations / terminations

18.4.3.2. IEC membership roster - An IEC roster will be maintained which will contain:

i.   Names of IEC members/ experts

ii.   Age and gender

iii.   Status of affiliation to institution (e.g., unaffiliated or affiliated)

iv.   Regular/ Alternate member to the IEC (if applicable)

v.   Correspondence related to changes in IEC membership with DCGI, CDSCO or DHR or any other concerned authority

vi.   IEC attendance roster

vii.   Agenda and Minutes of IEC meetings

18.4.4. Other documents

1. Standard operating procedures (SOPs)
2. Progress reports
3. Final reports
4. IEC reference material
5. Incoming and outgoing correspondence register
6. Documents related to Workshops & conferences organized by IEC
7. Continuing education for members & staff
8. SOP training and distribution logs
9. CD of soft copy and related documents of each proposal.

18.4.5. Maintenance of Closed Study Files

•   Once the study file is closed (following completion/ premature termination), the related study files will be shifted to the IEC Archival room.

•   All closed study files will be archived in the IEC archival room for a period of three years/ five years and more from the date of closure of the study as per CDSCO/DHR/Sponsor requirement.

• A log book for archival of study documents will be maintained.

18.4.6. 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 if authorized by Member Secretary/ Chairperson.

• Representatives of regulatory authorities may have access at all times.

• A log book of retrieval of documents will be maintained.

18.4.7. Disposal of Closed Files and Copies of Protocols and Documents Submitted for IEC Review

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

• Extra copies of protocols and documents submitted for IEC review and any other extra copies will be shredded by authorized IEC secretariat personnel after the IEC meeting without any notification to PI.

• A formal disposal log will be maintained, providing details of documents that will be disposed.

18.8. Annexure

Annexure 1 AX O1/SOP 18/V1   Document Request Form

Annexure 2 AX 02/SOP 18/V1   Log for disposal of study documents

Annexure 1: AX 01/SOP 18/V1

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 / Chairperson with date:	

Annexure 2: AX 02/SOP 18/V1

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

18.6. Flowchart

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