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|  | FERCI MODEL SOPs Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents | SOP 18/V1: Effective Date: aa/bb/cccc |
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Title: Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents

SOP Code: SOP 18/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

Prepared by:

| | |
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| Dr. Padmaja Marathe, FERC Member | (Signature with Date) |
|----------------------------------|-----------------------|

Reviewed by:


| | |
|----------------------------------|-----------------------|
| Dr. U. M. Thatte, FERC Secretary | (Signature with Date) |
| Dr. S. K. Kamat, FERC Treasurer | (Signature with Date) |

Approved by:

| | |
|---|-----------------------|
| Dr. Vasantha Muthuswamy, FERC President | (Signature with Date) |
| Dr. Nandini Kumar, FERC Vice President | (Signature with Date) |

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1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC), IEC 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 IEC administrative documents by the IEC Secretariat.


3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and IEC 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 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
 - Study approval letter
 - Reviewed and approved consent documents,
 - Amendments and any other correspondence


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- Study progress reports and interim reports,
- Serious adverse event report forms submitted by investigators,
- Any other reports
- IEC correspondance
- 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 IEC Administrative Records

The IEC records will include the following:

1. IEC 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 IEC member (GCP, SOP)
 - v. Documentation of resignations / terminations
2. IEC membership roster - An IEC roster will be maintained which will contain:
 - i. Names of IEC members
 - ii. Age
 - iii. Gender
 - iv. Evidence of qualifications
 - v. Role on the IEC
 - vi. Status of affiliation to institution (e.g., unaffiliated or affiliated)
 - vii. Regular/ Alternate member to the IEC (if applicable)
3. IEC mandate
4. Correspondence related to changes in IEC membership with DCGI, OHRP or any other concerned authority
5. IEC attendance roster

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6. Agenda and Minutes of IEC meetings
7. Standard operating procedures (SOPs)
8. Annual reports
9. Documents related to Workshops & conferences organized by IEC
(Continuing education for members & staff)
10. SOP training and distribution logs

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 IEC Archival room.
- All closed study files will be archived in the IEC 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/V1) 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.

4.5. 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 off 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 personnel after the IEC meeting without

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any notification to PI.

- A formal disposal log will be maintained, providing details of documents that will be disposed. (AX 02/ SOP 18/V1)

5. Annexures


Annexure 1 AX 01/ 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: | |

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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 |
|-------------|-------|--------------------------------|--------------|---------------------|--------------------------|-----------------------|--|
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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 |