



IHEC – MGMCRI SOPs
Maintenance of Active Study Files,
Administrative Records of the Ethics
Committee, Archival of Closed Files and
Retrieval of Documents

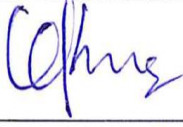

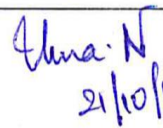

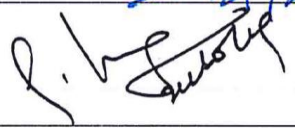


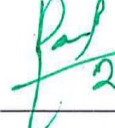
SOP Code: SOP 18/V2
Effective from 21/10/2019

Title: Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents

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Effective Date: 21-10-2019

SOP Constitution and Approval:

Prepared by:	Signature and Date:
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Dr. Uma Narayanamurthy, Additional Member Secretary, IHEC	 21/10/19
Reviewed by:	Signature and Date:
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Dr. Sivagnanam G, IHEC Co-Chairperson	 21/10/19
Approved by:	Signature and Date:
Dr. Jambulingam, P IHEC Chairperson	 21.10.19
Dr. Adithan C, Dean Research, SBV	 21/10/19
Dr. Ravishankar M, Dean, MGMCRI	 21/10



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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 Human Ethics Committee (IHEC), IHEC 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 IHEC administrative documents by the IHEC Secretariat of MGMCRI.

3. Responsibility

It is the responsibility of Member Secretary/Additional Member Secretary with assistance of Secretariat to ensure that all active study files and IHEC 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 IHEC 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
 - ✓ Study progress reports and interim reports
 - ✓ Serious adverse event report forms submitted by investigators
 - ✓ Any other reports
 - ✓ IHEC correspondence
- 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 IHEC Administrative Records

The IHEC records will include the following:

A. IHEC 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 IHEC member (GCP, SOP)
- v. Documentation of resignations / terminations

B. IHEC membership list - An IHEC list will be maintained which will contain:

- i. Names of IHEC members
- ii. Age
- iii. Gender
- iv. Evidence of qualifications
- v. Role on the IHEC
- vi. Status of affiliation to institution (e.g., unaffiliated or affiliated)
- vii. Regular/ Alternate member to the IHEC (if applicable)

C. IHEC mandate

D. Correspondence related to changes in IHEC membership with DCGI, OHRP or any other concerned authority

E. IHEC attendance list

F. Agenda and Minutes of IHEC meetings

G. Standard operating procedures (SOPs)

H. Annual reports

I. Documents related to Workshops & conferences organized by IHEC (Continuing education for members & staff)

J. 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 IHEC archival room.
- All closed study files will be archived in the IHEC 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/V2) if authorized by Member Secretary/Additional 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 IHEC Review

- At the end of the archival period, the closed files will be shredded and disposed of by authorized IHEC personnel.
- Extra copies of protocols and documents submitted for IHEC review and any other extra copies will be shredded by authorized IHEC personnel after the IHEC 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/V2).

5. Annexures

Annexure 1 AX 01/SOP 18/V2 Document Request Form

Annexure 2 AX 02/SOP 18/V2 Log for disposal of study documents



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Annexure 1: AX 01/SOP 18/V2
Document Request Form

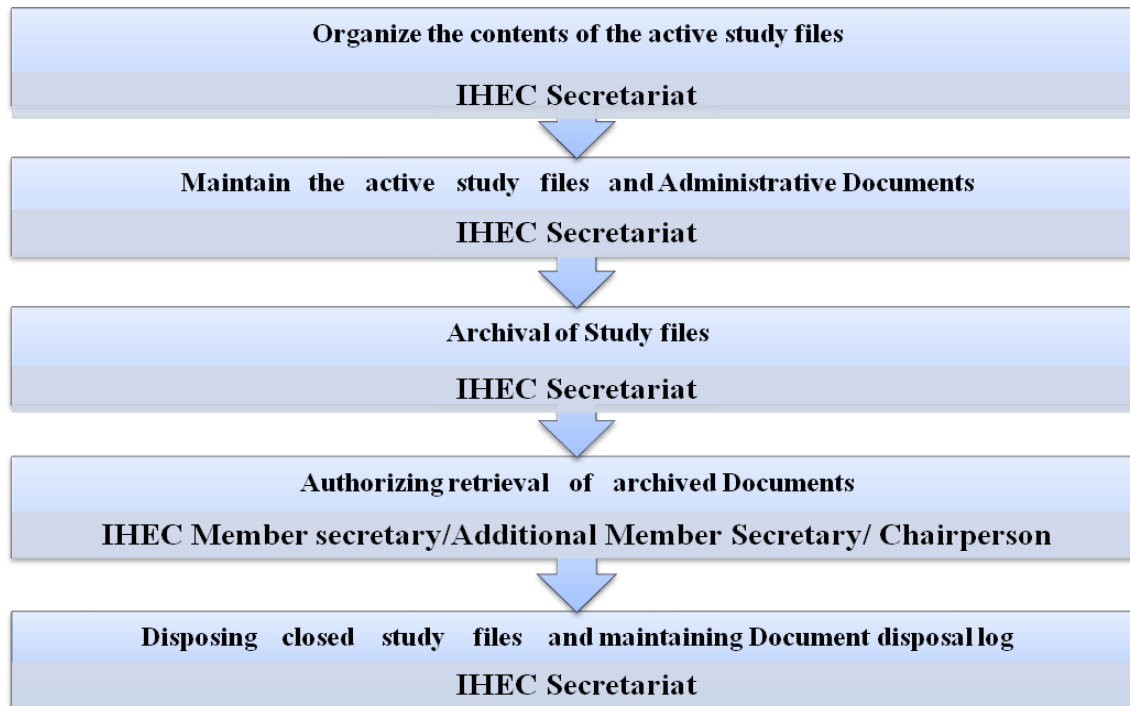
Project No.:	
Project Title:	
Name of Principal Investigator (PI):	
Requested by:	
Documents requested:	
Purpose of the Request	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary / Additional Member Secretary / Chairperson with date:	

Annexure 2: AX02/SOP018/V2
Log for disposal of study documents

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



6. Flowchart



7. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*
