

STANDARD OPERATING PROCEDURE [SOP]

RECORD KEEPING AND ARCHIVAL

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1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents presented to the IEC and storing of closed files and retrieval of documents.

2. Scope

This SOP applies to all protocol/study files and their related documents that are maintained in the IEC office and closed files.

3. Review of security, confidentiality and integrity of all proposals and associated documents and maintenance of administrative communication

- All efforts will be made to keep the records under lock and key for maintaining security, integrity and confidentiality using lockable steel cupboards [soft copies to individual members over online software is only visible/ accessible in their dashboard till a decision is not made by Member Secretary; post a decision, no member will have any access to previous research records online].
- Access to the keys of locked steel cupboards will be available only to Co-ordinator and Member Secretary. Fire safety measures will be in place along with regular pest control practices on the lines of Medical Records Department of the institute.
- The Office will maintain register of all projects/ requests submitted along with a register of all its Communications with stake holders [inward as well as outward register]
- Systems department of the institute will be responsible for maintaining the backup of email communications of the IEC email account [s].
 - The register will preferably include:

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- Protocol number [as per the inward number generated on submission of application along with date]
- Name [s] of Principal Investigator/ Co-Investigator
- Title of the project
- Ethical approval or recommendations for modifications or rejections with date
- Approval or otherwise of any changes to the project proposed by the researcher
- The terms and conditions if any, with approval of the project
- Whether review/ approval was by Full Committee or Expedited review
- Any action taken by the IEC, while monitoring the conduct of the research
- Communication with external agencies and Appointing Authority
- Any other communication with investigator [s] or stakeholder [s]
- With the use of online software for submission, review, communication and decision of the Committee, the Co-ordinator will function as IEC admin to regulate the use of online software for Committee purposes.
- Apart from online submissions, one hard copy of all the research projects [including amendments, SAE reports etc.] will be maintained by the Committee Office as Master file.
- The physical records [master file] will contain a hard copy of the application, any relevant correspondence between the applicant, other stake holders and the Committee, other material used to inform potential research participants and all approved documents.
- All documents of the IEC, including applications, membership, minutes of meeting and correspondence will be kept confidential and in accordance with Schedule Y and ICMR guidelines.
- Apart from above archival would also include monitoring reports, copy of communication with other stakeholders, self-assessment documents, accreditation related documents and any other relevant communication/ record depicting IEC work.
- To ensure confidentiality, all documents provided to IEC members, which are no longer required, will be disposed of in a secure manner, such as shredding or incineration. A register depicting record of the same will be maintained.

4. Archival of documents and records

- This will be done, preferably in a room available for archival of records, separately from IEC Office
- It will be the responsibility of IEC staff to ensure that all study files are prepared, maintained, and kept securely for a period of 5 years after the closure of the project (under a proper system that

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ensures confidentiality and facilitates retrieval at any time) [time period to vary depending upon the existing regulatory requirements from time to time].

5. Record retrieval policies and procedures

- Master files will be made available only after receiving the request in writing.
- This access to the records will be available only to Member Secretary and the Co-ordinator of the Committee during instances like requests from appropriate authority/ internal or external audit or accreditation team/ PI for duplicates etc.
- In case, any investigator needs a copy of any document from the master file, he/she should make a written request. After due approval from Member Secretary [usually within a week of getting the request], Co-ordinator will furnish a copy of the required document.
- A separate register/ file will be maintained in the Office, IEC that will document the access to the records of the Committee along with name of person, time, date and reason for the same [whenever needed].