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1. Purpose

The purpose of this SOP is to provide instructions for preparation and maintenance of IRB administrative documents, archival of closed and inactive files and retrieval of documents.

2. Scope

This SOP applies to maintenance, archival and retrieval of closed and inactive study files and study related documents and IRB administrative documents by IRB secretariat.

3. Responsibility

It is the responsibility of IRB secretariat to ensure that study files and IRB records are prepared, maintained, circulated and kept securely.

4. Flow chart


No.	Activity	Responsibility
1	Maintenance of IRB Administrative Records	IRB secretariat
	↓	
2	Maintenance of closed and inactive files	IRB secretariat
	↓	
3	Accessibility/ Retrieval	IRB secretariat
	↓	
4	Disposal of Closed Files and Copies of Protocols and Documents Submitted for IRB Review	IRB secretariat

5. Detailed Instruction

5.1. Maintenance of the IRB Administrative Records

The IRB records will include the following:

- IRB members' records
 - Appointment letter with TOR and acceptance letters of each member
 - Signed and dated confidentiality agreements and COI agreements
 - Updated Curriculum vitae (hard copy or soft copy)
 - Training records for each IRB member (GCP, SOP)

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- Documentation of resignations / terminations
- IRB membership roster - An IRB roster will be maintained which will contain:
 - Names of IRB members
 - Age
 - Gender
 - Evidence of qualifications
 - Role on the IRB
 - Status of affiliation to institution (e.g., unaffiliated or affiliated)
 - Regular/ Alternate member to the IRB
- IRB TOR
- Correspondence on changes of membership in IRB with DG or any other concerned authority
- IRB attendance roster
- Agenda and Minutes of IRB meetings
- Standard operating procedures (SOPs)
- Annual reports of SERO and EPHI-IRB
- Documents related to Workshops & conferences organized by IRB
(Continuing education for members & staff)
- SOP training and distribution logs


5.2. Maintenance of Closed and Inactive Files

5.2.1 Closed files

- All closed study files will be archived for a period of five years from the date of closure of the study: discussion and approval of the final report or premature termination of the project
- Log book for archival of study documents will be maintained. The files can be retrieved as needed

5.2.2 Inactive files

- Sponsors will be communicated by the secretariat to update status of the project, and reflect their opinions or provide recommendations to the IRB
- Final decision on the fate of the inactive study files will be provided by the IRB
- Inactive study files will be archived for a minimum of five years following determination of the IRB
- Log book for archival of study documents will also be maintained and retrieved when required

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5.3. 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 (EPHI-IRB AF 01-022/02.0) if authorized by Secretary/Chairperson.


- Representatives of regulatory authorities may have access at all times.
- A log book of retrieval of documents will be maintained.
- Log of Requests for Copies of IRB’s Documents (EPHI-IRB AF 01-027/02.0), Log of Copies for Original Documents (EPHI-IRB AF 02-027/02.0) and Form for requesting copies of original document (EPHI-IRB AF 02-027/02.0) will be used to access documents

5.4. Disposal of Closed Files & Copies of Protocols and Documents Submitted for IRB Review

- Extra copies of protocols and other documents submitted for IRB review will be shredded and disposed by secretary after the IRB decides on the protocol without any notification to PI
- At the end of the archival period, closed and inactive files will be shredded and disposed off by secretary
- Formal disposal log will be maintained for closed and inactive files, providing details of documents that will be disposed (EPHI-IRB AF 02-022/02.0)

6. Glossary


Administrative file	Documents related with the IRB function and members record.
Closed file	Supporting and approved documents (protocols, protocol amendments, informed consents, announcements, investigator and site information), records containing communication and correspondence with the investigator, and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the EPHI-IRB for which final report has been reviewed and accepted.
Inactive file	Study protocols declared “Inactive” by EPHI-IRB after six months period of no communication following expire date of approval.

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7. Reference

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.

8. Annex

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Annex 1: Log for Disposal of Study Documents
(EPHI-IRB AF 01-026/02.0)

Project No	Project Title	Name of PI	No of files	Date of IRB Approval	Date of Study Commencement	Date of Study Closure	Date of Disposal	Disposed by (Name & Signature)