9.1. Maintenance of Active Study Files

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1. Purpose

The purpose of this SOP is to provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by EPHI-IRB.

2. Scope

This SOP applies to all active study files and their related documents that are maintained in the IRB office.

3. Responsibility

It is the responsibility of IRB Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for at least five years under a proper system that ensures confidentiality and facilitates retrieval at any time.

4. Flow chart

No.	Activity	Responsibility
1	Organize the contents of the active study files	IRB Secretariat
	↓	
2	Maintain the active study files	IRB Secretariat

5. Detailed instruction

5.1. Organize the contents of the active study files

- Get the master copy of the study files.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
  - Original applications and any updates received during the study.
  - Investigator's brochures or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Approved documents (protocols, amendment, informed consent form, announcement materials, etc.)
  - Adverse effect reports or Investigational New Drug (IND) safety reports received
  - Continuing review reports
- Use a folder with the following on the cover:

- Title of the protocol
- The protocol number as assigned by the IRB Secretariat

- Put the following into each folder with the following information:
  - Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name (with e-mail & telephone addresses) and title
  - Application form of the IRB Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, announcement material and recruitment procedures, investigator bio data, any other material submitted by the investigator
    - Correspondence
    - Initial Approval with the final version of all above documents (protocol, Informed consent documents /ICD, Case record format/CRF etc.)
    - Revisions/Amendments
    - Adverse Events
    - Continuing Review, if applicable
    - Final report

5.2. Maintain the active study files

- Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the IRB Secretariat
- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package
- Keep all active and potential study packages in a secure file cabinet
- Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IRB
- Study files may remain active until six months after approval expire date if investigator adequately justifies for the delay of continuing review application. Study file remains active only if chairperson accepts the justifications for protocol reviewed through expedited process. Protocol approved by full board but with implementation plan yet to end in the future will also be decided by the chairperson but for the protocols whose implementation plan has ended will be determined through full board meeting
- Send all inactive study files to archive of secured inactive files
- Send all closed study files to archive of closed files
- Store the closed study files for ***at least five years*** after the study closure.

Note: For studies with multiple study sites, a member secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

6. Glossary

Active Study File	Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the EPHI-IRB.
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 a final report has been reviewed and accepted. Closed files are archived for a minimum of five years following completion of the study. These files can be retrieved as needed.
CRF	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
ICD	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Inactive file	Study protocols declared "Inactive" by EPHI-IRB after six months period of no communication following expire date of approval. Inactive study files are archived for a minimum of five years following approval expire date.
IND	Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
Master File	A file for storage of the originally signed and dated documents

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

None