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1. Purpose

To provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the CHH IRB

2. Scope

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

3. Responsibility

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

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	**Organize the contents of the active study files**	CHH IRB Secretariat
II	**Maintain the active study files**	CHH IRB Secretariat

5. Detailed instructions

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, advertising materials, etc.)
  - Adverse experience reports or Investigational New Drug (IND) safety reports received
  - Continuing review reports
- Use a folder with the following on the cover:

  The name of the sponsor
  The protocol number
  The CHH IRB REFERENCE number assigned by the CHH IRB Secretariat

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

5.2 Maintaining the active study files

- Assign the approved study files with unique identifiers (on a sheet of paper) established by the CHH 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 CHH IRB.
- Send all closed study files to archive.
- Store the closed study files for ***at least 5 years*** after the study closure.

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

6. ANNEX (none)

7. Reference

❖ World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

❖ International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

❖ National Ethical Guidelines for Health Research 2011 PNHRS