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1. Purpose

This Standard Operating Procedure (SOP) defines the process of archiving of completed, terminated, stopped or closed studies. This includes sponsor initiated as well as Investigator Initiated studies within the **Chong Hua Hospital Institutional Review Board (CHH IRB).** The SOPs developed in this SOP are adopted from the SOPs from FERCAP International.

2. Scope

This SOP covers the procedures of archiving of completed, terminated, stopped or closed studies. Studies which are inactive for 6 months will also be archived. This includes sponsor initiated as well as investigator initiated studies within **Chong Hua Hospital.** The scope also includes guidance on the retrieval of documents from the CHH IRB library of documents

3. Responsibility

It is the responsibility of CHH IRB Secretariat to ensure that all terminated study files are maintained and kept secure for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time. The member secretary has direct oversight over the staff secretary.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Selection of Files for archiving	Secretariat
II	Management for Archived Files	CHH IRB Secretariat and Chairperson
III	Sorting of Archived Files	CHH IRB Secretariat
IV	Storing the Protocol Documents	CHH IRB Secretariat
V	Management of file retrievals	CHH IRB Secretariat
VI	Maintenance of the log of retrievals	CHH IRB Secretariat

5. Detailed Instructions

5.1 Archived Files (Completed/Terminated/Inactive)

5.1.1 Archived Files Management

- Archived Files (Completed/Terminated/Inactive, Closed) are:
  a. Study protocols that have been completed with CHH-IRB-Approved Final Reports
  b. Study protocols declared "Inactive" by the CHH-IRB after a six (6) months period of no communication.
  c. Study protocols that have been terminated or closed
- Upon receipt of CHH-IRB Final Report Form, the CHH-IRB reviews it in accordance with SOP on Final Reports
- An archive number is assigned to the document by adding the date of the archiving to the original code of the study file using an orange sticker
- Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database
- During the annual inventory at year end, the Secretariat transfers the folder to the archives cabinet for safe storing

5.1.2 Sorting of Archived Documents

- Sorting is done once at the end of the year after the documents have been Completed/Terminated/Inactive for 6 months
- Sorting is chronologically done following the CHH IRB document identifier.

5.1.3 Storage of Archived Documents

- Documents are stored in the cabinets for archived files after they have been sorted with the CHH IRB document identifier duly logged in the protocol data base.
- After they have been kept in the active files cabinet for 6 months the files will be transferred to the archived files cabinet.

5.2 Documents Retrieval

5.2.1 Only the CHH-IRB Secretariat Secretary can retrieve active and archived document files. The CHH IRB member secretary has oversight of the staff secretary during the retrieval of the documents

5.2.2 Active or inactive study files can be borrowed, upon written request by the PI or the CHH-IRB personnel and are for CHH IRB Office use only.

5.2.3 A Borrower's Log is placed in a pocket on the study file folder cover, and contains the following information:

- Study File Code (Sponsor Protocol No. and IRB Reference No.)
- Date borrowed

- Number of borrower
- Name and Signature of borrower upon retrieval
- Signature of IRB Secretariat upon return
- Document copied
- Number of copies made
- Number of copies received

5.3 Confidentiality of Documents

5.3.1 Classification of Confidential Documents

The CHH-IRB classifies the following documents as "Confidential":

a. Study protocols
b. Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions, reviews)
c. Minutes of Meetings
d. Decisions, Action Letters/ Notification of CHH-IRB decision, Approval Letters
e. Study protocol-related communication

5.3.2 Access to Confidential Documents

Access to confidential documents is restricted by the CHH-IRB to members and staff but limited access can be provided to non-members who have a legitimate purpose to access the documents.

- All CHH-IRB members and staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure can have access to confidential documents upon approval of a request.
- Non-members can access specific documents upon formal request and completion/signing of Confidentiality Agreement for Non-Members. The form requires the approval of the CHH-IRB Chair. Regulatory authorities may have full access to the Confidential Documents if it is within the said authorities' mandate, and upon reasonable notice to make the files available.
- All requests for access are recorded by the Secretariat in the Borrowers Log before the documents are released.

5.3.3 Reproduction of Confidential Documents

– The Secretariat makes only the exact number of copies requested.
– Upon receipt of the copies requested, the recipient will sign the Log of Request
– Copies of documents, including draft and sequential versions should not be brought out of the CHH IRB Office
– Copy Authorization
  - Only members of the CHH IRB are allowed to ask for copies.

- Only staff members of the Secretariat of the CHH IRB are allowed to make such copies.
- The Secretary of the CHH IRB may ask for help, but should be responsible for confidentiality of all documents.

– Log of Request for Copies
  - A Log of Request for Copies (see ANNEX 1 Form HRP-IRB-030) must be kept by the Secretariat.
– Copies of CHH IRB's documents requested by non-members of the CHH IRB (including the Secretary) can only be given after the permission from the Chairperson of the CHH IRB and the person requesting for the document signs a confidentiality agreement form
– Copies made for non-members of the CHH IRB must be recorded in both the Log of Request for Copies of CHH IRB's documents.

5.4 Maintenance of Log of Copies

– The log should include: the name and signature of the individual receiving the copy; the initial of the CHH IRB Secretary who made the copy; the number of copies made and the date that the copies were made
– The Secretariat ensures the diligent recording of all document copies issued in the Log of Request for Copies of Documents
– This log is filed in a separate folder labeled Log of Copies Issued.

6. ANNEX 1: Log of Request for copies of CHH IRB's Documents

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

LOG OF REQUEST
FOR COPIES OF CHH IRB'S DOCUMENTS

Form HRP-IRB-030 ver05

Study File Code (Sponsor Protocol No. and IRB Reference No.)	Date borrowed	No. of borrower	Name & Signature of borrower upon retrieval	Signature of IRB Secretariat upon return	Document copied	No. of copies made	No. of copies received

LOG OF REQUESTS FOR COPIES OF CHH IRB'S DOCUMENTS Control #: 1

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