1. Purpose

To describe Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to archiving of terminated, inactive and completed studies.

2. Scope

This SOP provides instructions to the Secretariat related to requirements for archiving completed study protocols after the final report or other relevant documents have been received.

3. Responsibility

It is the responsibility of the CHH IRB Staff, under the supervision of the Member-Secretary, to archive in an orderly manner all protocol files that have been terminated, completed or are no longer active. They are kept together in a designated cabinet, separate from the cabinet for active files, in the CHH IRB office.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Identify inactive protocol files	CHH IRB Secretariat	7 days
Step 2: Affix appropriate label to file for archiving & record in Database of Archived Documents	CHH IRB Secretariat	
Step 3: Transfer files to the archiving cabinet for inactive file or update the drive labeling it as “Inactive”	CHH IRB Secretariat	
Step 4: Update protocol database	CHH IRB Secretariat	
Step 5: Communicate archiving decisions to PI thru form “Notice of Archiving”	CHH IRB Secretariat	

5. Procedures

Step 1- Identify inactive protocol files

- Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by the CHH IRB.
- Studies are also classified as inactive when no further communication has been received by the CHH IRB after **two years**.
- Studies that underwent early termination are subsequently categorized as inactive upon receipt of relevant information about termination.
- The CHH IRB Staff removes the protocol file folders from the storage file cabinet for active studies, checks its contents and updates the protocol file index.
- The CHH IRB Staff shreds extra copies that are not needed.

Step 2- Affix appropriate label to files for archiving & record in Database of Archived Documents:

- The CHH IRB Staff labels protocol files as inactive by reprinting the protocol labels in red background paper and re-attaching them to the files with the addition of the year the study is declared inactive.
- The CHH IRB Staff logs the protocol number and other protocol identifiers in the Database of Archived Documents.

Step 3- Transfer files to the archiving cabinet for inactive files:

- The CHH IRB Staff transfers the protocol file to the designated secure archive cabinet for inactive files.
- As in active study files, protocol files in the secure storage cabinet for inactive studies are arranged sequentially.
- Protocols are archived for **3 years**. Archived protocols can be accessed in accordance with SOP 4.8 on Maintaining Confidentiality of Study Files and IRB Documents.
- After 3 years in the archive, the protocol files may be transferred to the hospital archive or shredded.

Step 4- Update protocol database: The archiving data should be entered accordingly in the protocol database. The CHH IRB Staff reviews entries in the protocol database for the protocol for archiving, to check if all fields are completely filled.

Step 5- Communicate to PI regarding Archival: Communication to the PI regarding Archival will be done thru Notice of Archival. The CHH IRB Staff reviews entries in the protocol database for the protocol for archiving, to check if all fields are completely filled.

6. History of SOP

Version No.	Date	Authors	Main Change
1	-	-	-
2	01 September 2014	Mr. Romel V. Cabazor	First Draft
3	01 October 2014	Mr. Romel V. Cabazor	Change of IRB SOP in accordance to PHREB SOP format
4	01 October 2014	Mr. Romel V. Cabazor	Revised IRB SOP in accordance to PHREB SOP Format
5	01 January 2017	Dr. Cheryl K. Bullo	Revised CHH IRB SOP from Version 04 to Version 05
6	02 October 2017	Atty. Geraldine Cajilig	Revised CHH IRB SOP in accordance to 2017 DOH REC SOP ver02 Template
7	04 January 2021	Atty. Geraldine Cajilig	No change
8	04 January 2024	Atty. Geraldine Cajilig	No change
9	21 August 2024	Atty. Geraldine Cajilig	No change

7. Reference

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