1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to the management of active study files.

2. Scope

This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the IRB before completion of the study.

3. Responsibility

It is the responsibility of the CHH IRB Secretariat to manage all protocol submissions and documents that reflect all IRB actions and organize them in an orderly manner. The CHH IRB Secretariat also manages the maintenance and storage of all IRB documents and records.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: File protocol and other protocol related documents In an organized manner	CHH IRB Staff	7 days
Step 2: Update protocol file folder regularly as documents come or are produced	CHH IRB Staff	
Step 3: Store properly labeled protocol file folder in the appropriately labeled file storage google drive; electronic documents will be placed in the Protocol Database	CHH IRB Staff	
Step 4: The electronic protocol database is updated with PI submissions and IRB decisions/actions	CHH IRB Staff	

Step 5: Keep other IRB files in google drive/desktop file	CHH IRB Staff	

5. Procedures

Step 1- File protocol and other protocol-related documents in an organized manner

- Protocol files are considered active from the moment the protocols are received for initial review until such time they are inactivated either by its completion or termination or its withdrawal from the review process. Active protocol files are either those undergoing IRB review process or IRB-approved ongoing studies. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval.
- Study Protocols are identified using a unique identification number known as IRB Reference No. given by the CHH IRB as described in SOP 2.1 on Management of Initial Submission.
- The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index per type of submission (e.g. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):
    - All versions of study protocol
    - Protocol-related documents (ICF, CRF, recruitment materials, patient diary, IB, etc.)
    - Principal investigator and co-investigators' CVs and valid GCP Training Certificate, if required
    - Reviewers' assessment forms
    - Decision letters (notification letters or approval letter/s – initial and renewal)
    - Post-Approval submissions (protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report) and corresponding reviewers' assessment and IRB decision letters
    - Participant queries/complaints, if any
    - Site Visit Reports, if any
    - Miscellaneous communication related to the protocol
    - Final report
- Hard copies are placed in a file in a durable binder all protocol related documents in chronological sequence with the most recent file/document at

the top, Update the Protocol File Index whenever a new document is filed. A label is stuck on the binder which contains the following data: IRB Reference no., Protocol code no., title of the protocol, name of PI, sponsor and date of review. Electronic copies of the files are stored in a similar fashion in the google drive. (See SOP 4.9)

Step 2- Update protocol file folder regularly as documents come or are produced:
The CHH IRB Staff logs every protocol-related document received. This log should contain at least the following items:

- Date/Time received
- Document Received
- IRB Reference No.
- Principal Investigator
- Initial of Person who received the document
- Type of Submission (e.g. Protocol for Initial Review, Resubmitted Protocol, Application for Protocol Amendment, Protocol Violation/Deviation Report, SAE Report, etc.)
- IRB Action Required.

The CHH IRB Staff also logs protocol and protocol-related documents when they are forwarded to IRB members for review. This log should contain the following items:

- Date/Time Sent
- Sending Person
- Mode (e.g. e-mail, courier, etc.)
- Receiving Person
- Content of Document
- Remarks

Protocol-related paper files/documents (hard copies) are added to the protocol file folder on the day that they are submitted or accomplished (assessment forms, IRB decision letters). The binders are kept in locked cabinets. Electronic copies of the files are stored in a similar fashion in the google drive. (See SOP 4.9)

Step 3- Store properly labeled protocol file folder in the google drive/desktop file

- For the period of transition when paper copies are still being stored, these will be filed securely in a cabinet, with access limited only to CHH IRB Chair and Secretariat. The CHH IRB Staff keeps the keys of file storage cabinets.
- Active files can be accessed outside of regular protocol review in accordance with the SOP 4.8 on Maintaining Confidentiality of Study Files.
- The electronic copies of the database can be accessed by passwords that are shared only with the IRB staff. (See SOP 4.9)

Step 4: The electronic protocol database is updated with PI submissions and IRB decisions/actions

Step 5: Keep other IRB files in Google drive folder and in desktop file

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Dr. Cheryl K. Bullo	First draft
2	01 January 2014	Dr. Cheryl K. Bullo	Change in the logo from CHH to CHH IRB logo Revised SOP and form numbering
3	01 September 2014	Dr. Cheryl K. Bullo	Change of IRB sop in accordance to PHREB SOP Format
4	01 October 2014	Dr. Cheryl K. Bullo	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	Dr. Cheryl K. Bullo	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 template
7	04 January 2021	Dr. Cheryl K. Bullo	No change
8	04 January 2024	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance with REC re-accreditation and Survey on 30 June 2023
9	21 August 2024	Maria Teresa Cañete	Revised CHH IRB managing active file from “storage cabinet” to Google drive/desktop file”

7. Reference

- 2017 Department of Health – SOP Version No. 2
- 2020 PHREB SOP Workbook