1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to the management of Protocol Database.

2. Scope

This SOP provides instructions related to the management of Protocol Database which serves as the repository of all files, including protocol submissions, all documents that reflect all actions taken by the IRB before completion of the study. There will be a transition period where paper files will be converted into electronic copies and submitted via form or email, also digitally. It also provides instructions for the maintenance and storage of other IRB documents that include SOPs, CHH IRB membership files, agenda and meeting minutes, relevant international and national regulations and guidelines, etc.

3. Responsibility

It is the responsibility of the CHH IRB Secretariat to manage the Protocol Database: 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: Hard copies of File protocol and other protocol related documents are placed in physical binders in IRB office; Electronic copies are uploaded into google drive.	CHH IRB Staff	7 days
Step 2: Update protocol file folder regularly as documents come or are produced; google drive is also updated simultaneously.	CHH IRB Staff	
Step 3: Backup of Database	CHH IRB Staff	every week
Step 4: Maintenance of related databases	CHH IRB Staff	monthly

5. Procedure

Step 1- Protocol database: Updated documents facilitate protocol monitoring since these include due dates of reports and determining active protocol status. Protocol and related documents must have the following data in searchable format

- **Contents:** The Protocol database contains a list of all protocols received by the IRB; the electronic file has sufficient columns to contain all protocol-related information, PI submissions and action taken by the IRB from initial review to final report approval. The Study Protocol or related document is first entered into the CHH IRB protocol database using its IRB Reference number, title, names of PI and sponsor, etc.

It should have at least the following fields:

- Protocol Code
- Protocol title
- Department
- PI and details
- Submission date
- Full board or Expedited Review date
- Primary Reviewers
- Review decision

- Full Committee review meeting date
- Approval date and expiration date
- Due date for progress report
- Date of approval
- Communication letters
- Protocol Deviations
- SUSAR's/ SAE
- Date of final report

- **Access:** The database should use an electronic format and should be password-protected so that the database is secure. The CHH IRB Staff should also maintain a back-up copy of the protocol database in an external drive kept at the office of the IRB Chair in CHH – Mandaue, that is updated at every end of the regular monthly meeting.

Step 2- Updating the Database: The database is updated within 7 days of receipt of documents. Care is done to ensure no loss of data.

Step 3- Backup of database: The entire database is backed up weekly via an external drive. Regular antivirus subscription is ensured; care is done to maintain the database safe against hacking.

Step 4- Maintenance of Related Databases: Keep other IRB files that include the SOPs, Membership Files, international and national guidelines and regulations, etc. in the office cabinets and regularly update them for reference of the IRB members.

6. History of SOP

Version No.	Date	Authors	Main Change
1	04 January 2024	Dr. Maria Theresa Canete	First draft
2	21 August 2024	Dr. Maria Theresa Canete	No Change

7. Reference

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