1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedure for managing the submission of the initial protocol package for review – from the time of receipt to filing of the initial protocol package in the Google drive/PC folder..

2. Scope

This procedure applies to all protocols submitted to the CHH IRB for ethical review.

The CHH IRB accepts the following protocols for review: 1) Chong Hua Hospital funded researches, 2) researches done in Chong Hua Hospital, 3) researches referred from the PNHRS, PCHRD, DOST, PHIC, PHREB, DOH, FDA, CHED, industry organizations, etc on the condition that the host hospital/institution where the proposal will be done, accepts the review of CHH IRB and agrees to abide by the rules and regulations that the CHH IRB follows. The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept CHH IRB review.

3. Responsibility

The CHH IRB Secretariat manages all protocol submissions to the CHH IRB. It covers the actions to be done from the time of submission to the filing of the initial protocol package in the Google drive/PC Folder.

4. Flowchart

ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
Step 1: Receive the initial protocol package for review and check the completeness of the documents submitted	CHH IRB Staff Secretary	To be done within 7 working days
Step 2: Assign a permanent code to the protocol package	CHH IRB Staff Secretary	
Step 3: Give a document receipt form of the review application form to the person submitting package	CHH IRB Staff Secretary	
Step 4: Determine the type of review and assign the primary reviewers	Chair/Member Secretary	
Step 5: Prepare the protocol review package for distribution to the primary reviewers	Chair/Member Secretary	
Step 6: Log the received protocol package in the protocol database	CHH IRB Staff Secretary	
Step 7: File the initial protocol package in a Google drive	CHH IRB Staff secretary	

5. Procedures

Step 1- Receive the initial protocol package for review and check the completeness of the documents submitted

- Ensure that the Initial Review Application Form and the **Protocol Summary Sheet** (form 2023-2.1-HRP-IRB-036-PROTOCOL SUMMARY SHEET) are completely filled up, signed and dated by the researcher.
- For Investigator Initiated Study/Resident Papers (on training), and fellows, require submission of the endorsement from the department and the technical review committee (Form 2023-2.1-HRP-IRB-009-IRB APPLICATION INFORMATION SHEET).
- All **Chong Hua Hospital** funded protocols need technical review. The Technical Review Committee should have addressed the technical issues in the study protocol.
- For non - **Chong Hua Hospital** funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.
- Upon submission of the initial protocol for **CHH IRB** review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet.
- We have updated the forms of the initial application package, where provisions for electronic submission

Step 2- Assign a permanent code to the protocol package

- For efficient file management, it is necessary to use a unique identifier to refer to this file, the IRB Reference Number. This code number is given as follows: IRB-YYYY-NNN (NN- chronological number based on order of receipt for the year, YYYY- the year protocol was received).
- For example, if the protocol entitled "Clinical Drug Trial of XYZ on Pediatric Patients" is the first protocol received in 2023, the code **IRB-2023-001** should be used to identify this protocol. The code will be communicated to the researcher/principal investigator in all communications regarding the protocol.

- Investigator initiated studies will have as a suffix "IRBi" to differentiate it from sponsor-initiated studies.
- For the same protocol with different PI's, use the same code differentiated by suffixes.
- For example, if the protocol above is done by two PI's, it should be coded as IRB-2023-001 A and IRB-2023-001 B.

Step 3- Give a duplicate copy of the review application form to the person submitting the package: Instruct the person submitting the package to inform the researcher/PI to use the IRB Reference Number to identify the protocol in all submissions and in all his/her communications to the CHH IRB.

Step 4- Determine the type of review: There are three (3) types of review:

- Exempt from review – for negligible risk protocols
- Expedited review – for low-risk protocols
- Full-Board review – for medium to high-risk protocols

Criteria for study protocol to be **Exempt from Review:**

- Research about public behavior (voting trends, opinion surveys, etc)
- Evaluation of public programs by the agency itself
- Quality control studies by the agency itself
- Standard educational tests and curriculum development
- Surveillance functions of DOH
- Historical and cultural events
- Research involving large statistical data without identifiers
- Research not involving humans or human data

Criteria for Expedited review

- Minimal/low risk health research that requires personal information:
- About a topic that should not result in causing social stigma
- Does not involve vulnerable populations
- Retrospective studies using anonymized data from medical records
- Studies using simple questionnaires without identifiers

- Laboratory research that uses anonymized human tissue/specimen

Full-Board review may be about the following:

- Human health research involving medium to high risks to human participants
- Intervention studies involving experimental treatments like clinical trials
- May involve vulnerable populations who should be protected
- Involves private information that may cause stigma

Assigning a Primary Reviewer

- The Chair/Member-Secretary designates at least two IRB members (one medical/scientific and one non-medical) to be the primary reviewers of the protocol and the informed consent form regardless of whether the type of review is expedited or full board.
- Primary reviewers are selected on the basis of expertise related to the protocol.
- The medical/scientific reviewer analyzes the scientific and ethical aspects of the protocol using the Protocol Assessment Form while the non-medical member focuses on the ICF and informed consent procedure using the Informed Consent Assessment Form.
- If the IRB membership does have the needed expertise, the Chair/Member Secretary chooses from the roster of Independent Consultants. If none is available a consultant with the needed expertise is recruited as per SOP on Selection of Independent Consultant.

Step 5- Prepare the protocol review package for distribution to the primary reviewers: The timeline from receipt of complete package to distribution to primary reviewers is within 7 working days. The initial protocol review package consists of all the documents in the initial protocol package plus blank copies of the Protocol Assessment Form**,** with the transmittal letter to the primary reviewers.

Step 6-Log the received protocol package in the protocol database: There is a need for subsequent entries in the database as per SOP 4.6 Managing Active Files.

Step 7- File the initial protocol package in a properly labeled Protocol File folder: For **paper-based forms and folders**, the binder has all pertinent documents, and these are placed in the Active Study File cabinet. A protocol file index that should serve as a Table of Contents of each protocol file.

On the side of the file binder, write the following:

- IRB Reference Number
- Full title of the research
- Name of the Principal Investigator
- Sponsor Protocol Code Number
- Name of the Sponsor
- Date reviewed

A period of transition will be made for **electronic submission** and archiving of all forms. A Google drive will hold all documents, whether they are scanned from paper or are filled out electronic forms. Documents pertinent to one protocol will be in one folder in the drive. After the period of transition, all submissions will be done electronically.

6. History of SOP

Version No.	Date	Authors	Main change
1	01 September 2010	Rev. Msgr. Joseph Tan, PC	First Draft
2	01 January 2014	Dr. Manuel Emerson S. Donaldo	Change in the logo from CHH to CHH IRB logo Revised SOP and form numbering
3	01 September 2014	Dr. Manuel Emerson S. Donaldo	Change of IRB SOP in accordance to PHREB SOP Format
4	01 October 2014	Dr. Manuel Emerson S. Donaldo	Revised IRB SOP in accordance to PHREB SOP Format Revised IRB Application forms for Sponsor Initiated study and Investigator study
5	01 January 2017	Dr. Elaine L. Gallardo	Revised CHH IRB SOP form version 04 to version 05
6	02 October 2017	Mr. Romel V. Cabazor	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template Additional protocol summary sheet form in the IRB Application form for sponsor initiated study and Investigator Initiated study
7	04 January 2021	Mr. Romel V. Cabazor	No change
8	04 January 2024	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance with the action plan submitted for PHREB/FERCAP re-accreditation
9	21 August 2024	Atty. Dean G. Decal Dr. Maria Teresa Canete	Revised; independent consultant can be tasked to review protocols esp. if needed expertise is not amongst the members of IRB.

7. References

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