1. Policy Statement

The CHH-IRB shall have a chair, appointed by the appointing authority of the Institution (Chong Hua Hospital).

The CHH-IRB shall also have a vice-chair, and member-secretary who shall be selected among the members by election in a special meeting initially presided by the incumbent chair.

2. Objective of the Activity

This activity ensures that the CHH-IRB officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

3. Scope

The scope of this SOP includes the selection of Chair, Vice-Chair and Committee Secretary. It starts with the appointment of a new Chair by the appointing authority and ends with the filing of appointment documents of the officers.

4. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: The COO thru the Medical Director appoints a new Chair for the CHH IRB	COO/Medical Director
Step 2: Incumbent CHH IRB Chair calls for a special meeting for the election of officers	Incumbent CHH-IRB Chair
Step3: Nomination of Vice Chair and Member Secretary	CHH-IRB Members
Step 4: Election of Vice Chair and Member Secretary	CHH-IRB Members
Step 5: Endorsement of the list of officers to the Appointing Authority	CHH-IRB Chairman
Step 6: Receipt of Appointment of new officers from the Appointing Authority	CHH-IRB Staff
Step 7: Signing of Conforme	CHH-IRB New Officers
Step 8: Filing of appointment documents (SOP on Managing Active Files (SOP #4.6)	CHH IRB Staff

5.Procedures

Step 1- The Chief Operating Officer through the Medical Director appoints a new Chairman for the CHH-IRB: After the three (3) year term of the incumbent chairman, the Chief Operating Officer (COO) through the Medical Director appoints a new chairman or re-appoints the incumbent chairman to head the CHH-IRB for another three (3) year term**.**

Step 2- Call for a special meeting: The CHH-IRB Staff upon instruction of the incumbent Chair sends a Notice of Meeting (Form 2023-HRP-IRB-027-IRB Agenda Template) to all members of the CHH-IRB Copy stating the purpose of the meeting to be the election of (an) officer/s.

Step 3- Nominations: The newly elected Chair leads the nomination process for the Vice-Chair and Member Secretary who are also members of the CHH-IRB. The Vice Chair and Member Secretary are nominated by the members of the CHH-IRB.

Step 4- Election: Election of Vice Chair and Member Secretary shall be by secret ballot and is based on the majority rule. A tie shall be settled by a "toss-coin" or any alternative process. The Chair, Vice Chair and Member Secretary should be highly-respected individuals within or outside the institution, fully capable of managing the IRB and ensuring fairness and impartiality in dealing with matters brought by the IRB. The Chair, Vice Chair, and Member Secretary should be trained in Basic and Advance Research Ethics and Good Clinical Practice (GCP), and should have been a member for at least one-year.

Step 5- Endorsement: The list of elected officers is submitted to the Chief Operating Officer (COO) through the Medical Director for appointment.

Step 6- Receipt of the Appointment of new officers:

- The CHH-IRB Office receives the appointment papers of the elected officers that contain the role and responsibilities of the specific officers and the corresponding term of office.
- The COO thru the Medical Director of the **Chong Hua Hospital** is responsible for appointing the CHH IRB Officers with the due consideration to the IRB recommendations.
- The Medical Director issues an appointment letter that identifies the CHH IRB Officers

Responsibilities of the IRB Chair

- Ensures that all IRB members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education thereafter
- Obtains administrative and logistics support for the sustained operations of the IRB
- Approves the agenda and presides over IRB review meetings
- Selects suitable (somebody with related expertise) member/independent consultant to be the primary reviewer of a protocol whether by full board or

expedited review, and ensures that aforementioned member does not have conflict of interest.

- Manages complaints from study participants, authorities or the general public
- Designates a member or group of members to investigate in cases of complaints or report of major non-compliance
- Ensures that CHH IRB is perceived as fair and impartial, and complies with institutional, national and international standards
- Represents the CHH IRB in various local, national and international meetings and conferences.
- Prepares the Annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) and approved by the medical director
- Ensure adherence to quality standards to maintain the accreditation status

Responsibilities of the IRB Vice Chair

- Able to assume the position and the duties and responsibilities of IRB Chair in the event of a temporary or permanent unavailability of the IRB Chair
- Presides over the IRB review meetings in the event the IRB Chair has Conflict of Interest relative to the protocol for deliberation.

Responsibility of the Member-Secretary

- Supervises the CHH IRB staff related to good IRB office management
- Selects suitable (somebody with related expertise) member or independent consultant to be the primary reviewer of a protocol whether by full board or expedited review, and ensures that aforementioned member does not have conflict of interest.
- However, if the member secretary is not a medical doctor, the designation of a primary reviewer should be with the help of the chairman or vice-chairman of the IRB.

- Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair
- Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting
- Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions,
- Supervises the CHH IRB Staff in the preparation of the meeting agenda and minutes
- Supervises the CHH IRB Staff in the preparation of the annual report of the CHH IRB to be submitted to the IRB Medical Director of Chong Hua Hospital, DOH, PHREB and other bodies.
- Ensures good IRB documentation and archiving.
- Ensures overall IRB compliance with good clinical practice.
- Ensures good financial management of IRB resources.

IRB Secretariat- The CHH IRB secretariat is composed of the Member-Secretary and two (2) administrative staff who are employees of the **Chong Hua Hospital.** Their responsibilities include:

- Organizing an effective and efficient tracking procedure for each proposal received. The submission procedure will migrate to electronic format in the near future, and the secretariat will be directly responsible for this.
- Preparation, maintenance and distribution of study files; The filing and maintenance of files will migrate to electronic format in the near future, and the secretariat will be directly responsible for this.
- Preparation and maintenance of meeting agenda**(see template for Meeting Agenda)** and minutes
- Maintaining good IRB documentation and archiving procedures: The Archiving procedure will migrate to electronic format in the near future, and the secretariat will be directly responsible for this.

- Communications with CHH IRB members and Investigators
- Organizing the preparation, review and distribution of SOPs and guidelines in their latest version
- Providing the necessary administrative support for IRB-related activities to the Chair of the IRB
- Maintaining a library of relevant resources, materials and references. This includes the following essential references ICH GCP R2E6 (2016), DOH AO 2020-0010 (Conduct of Clinical Trials), PNHRS Law

Step 7- Signing of Conforme: The CHH-IRB staff notifies the officers of their appointments and the need to sign the conforme. The concerned officers forthwith report to the CHH-IRB office to sign the conforme documents.

Step 8- Filing of appointment documents: The CHH-IRB Staff files the appointment papers accordingly (see SOP for Managing of Active Files (SOP 4.6)

6. History of SOP

Version No.	Date	Authors	Main Change
8	04 January 2024	Atty. Dean Decal	First draft from SOP 1.1
9	25 August 2024	Atty. Dean Decal	No Change

7. References

- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- Department of Health (DOH) SOP Version 2 2017