	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD CHH IRB	
Version No: 09 Date of Approval: 08/21/24 Date of Effectivity: 08/21/24	**SOP 2.5 FULL BOARD REVIEW**	

1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH-IRB) procedures when the protocol submissions are classified for full board review.

2. Scope

This SOP applies to the CHH-IRB full board review and approval of study protocols during initial and continuing review.

3. Responsibility

Full board review is the joint responsibility of all CHH-IRB members who review and make decisions on the protocol related documents during a convened full board meeting.

In general, full board review is done for protocols that involve medium to high risk interventions to humans like experimental treatments in clinical trials that may involve vulnerable human subjects.

4. Flowchart

ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
Step 1: Determine if the submission should undergo full board	Secretariat/Member secretary/chair	7 days
Step 2: Assign primary reviewers (medical/scientific and non-medical/Non-scientific members.)	Member-Secretary/ Chair	
Step 3: Send the protocol package to the primary reviewers	CHH IRB Staff	
Step 4: Review the documents with the use of the assessment forms	Primary reviewers	7 days
Step 5: Return the accomplished assessment forms to the secretariat	Primary Reviewers	
Step 6: Discuss and decide on the protocol and related documents during a convened full board meeting	IRB Members	Full Board Meeting
Step 7: Communicate the IRB decision to the PI and allocate 4 weeks for the PI to comply	CHH IRB Staff	7 days
Step 8: File copies of the documents in the protocol file folder and update the protocol database	CHH IRB Staff	

5. Procedures

Step 1- Determine if the submitted protocol documents should undergo full board review: The Chair/ Member Secretary screens the protocol to identify those that should be discussed at full board.

- For initial review: The Chair/ Member Secretary goes over the submitted protocol and decides if it should undergo full board review based on assessment of risks.

- The following are types of protocols that should be reviewed at a convened full board meeting:

  - Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
  - Phase 4 intervention research involving drugs, biologics or device
  - Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm
  - Intervention protocols involving vulnerable subjects (patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review
  - Protocols that involve collection of identifiable biological specimens from vulnerable groups, etc.

- For resubmitted documents: IRB decision for major modification of documents (protocol, ICF, etc.) requires full board review of revisions.

- The following continuing review submissions should undergo full board review:

  - Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
  - Major amendments that change the risk/ benefit ratio
  - Major protocol violations

- Progress reports of ongoing studies that involve medium to high risks to human subjects/ participants
- Onsite SAEs or SUSARs that involve safety issues

Step 2- Assign primary reviewers (medical/scientific and non-medical/non-scientific members) to review the protocols.

- The Chair/ Member Secretary: Assign a Medical/ Scientific Reviewer (IRB member or Independent Consultant) to review the scientific and ethical merits of the protocol related documents. Assign a non-medical/ non-scientific member to review the ICF.

Step 3- Send the protocol package to the primary reviewers

- The CHH IRB Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 7-day deadline. If not, other primary reviewers are identified.
- The CHH IRB Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding study assessment forms and forwards them to the designated reviewers.

Step 4- Review the documents with the use of the study assessment forms.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms. The IRB primary medical reviewer accomplishes both the protocol and ICF assessment forms while the primary non-medical reviewer evaluates informed consent documents by using the Informed Consent Assessment Form.

- The Primary Reviewers recommend the type of decision for initial review of protocol related documents:

    - Approved
    - Minor modification required
    - Major modification required
    - Disapproved
- Primary reviewers should also check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements:
- Consider whether the study and training background of the principal investigator are related to the study.
- Look for disclosure or declaration of potential conflict of interest.
- Determine if the facilities and infrastructure at the study site are suitable for the study.

Step 5- Return the accomplished assessment forms to the Secretariat: The Primary Reviewers sign, date the assessment form/s and return them to the Secretariat on the day of the regular full-board meeting. The Secretariat checks completeness of the assessment forms and files it accordingly.

Step 6- Discuss and decide on the protocol and related documents during a convened full board meeting.

- Conduct a full board meeting to discuss and make a decision about the protocol and related documents. (Refer to SOP No. 4 on Conduct of a Full Board Meeting)
- The members of the CHH IRB attending the full board meeting have to approve the following:
    - Principal and Co Investigators and members of the research team
    - Protocol
    - Informed Consent
    - Advertisements or recruitment materials
    - Study sites covered by the application

- The CHH IRB members vote on specific items to arrive at a decision as follows:

    - Approval (when no further modification is required)

    - Minor modification (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)
    - Major modification (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)
    - Disapproval (due to ethical or legal concerns) Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

- If the study is approved, the CHH IRB determines the frequency of continuing review.
- All meeting deliberations and decisions regarding a protocol are noted in the meeting minutes. (Refer to SOP No. 4 on Preparation of Meeting Minutes)

Step 7- Communicate the IRB decision to the PI and allocate 4 weeks for the PI to comply: All CHH IRB decisions are communicated to the PI.

- Approval: The CHH IRB Staff prepares the Proforma of Letter of Approval to be signed by the Chair.
- Minor modification: The CHH IRB Staff prepares the Notification Letter to inform the PI of the required revisions in the protocol, ICF or any related document. The resubmitted documents undergo Expedited Review before approval is granted. The Chair/Member-Secretary reviews and checks compliance to recommendations of the resubmitted documents, before granting approval.
- Major Modification: The CHH IRB Staff prepares the Notification Letter to inform the PI of any required revisions in the protocol, the ICF or related document. The resubmitted documents are referred to Primary Reviewers and discussed at Full Board Review, once more before approval is granted.

- Disapproval: The CHH IRB Staff prepares the Notification Letter to inform the PI of CHH IRB decision. The reasons should be clearly stated in the notice. (Refer to SOP No. 4 on Communicating IRB Decisions to the Researcher/PI)

5.1. File copies of the documents in the protocol file folder and update the protocol database.

- The CHH IRB Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The CHH IRB Staff updates the protocol database.

6. History of SOP

Version No.	Date	Authors	Main Change
1	-	-	-
2	-	-	-
3	01 September 2014	Dr. Manuel Emerson S. Donaldo	First draft
4	01 October 2014	Dr. Manuel Emerson S. Donaldo	Revised IRB SOP in accordance to PHREB SOP Format
5	01 January 2017	Rev. Fr. Benedicto P. Tao	Revised CHH IRB SOP from 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
7	04 January 2021	Mr. Romel V. Cabazor	No change
8	04 January 2024	Mr. Romel V. Cabazor	No change
9	21 August 2024	Mr. Romel V. Cabazor	No change

7. References

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