1. Purpose

To describe the procedures of Chong Hua Hospital Institutional Review Board (CHH IRB) when it conducts a full board meeting to review protocol submissions.

2. Scope

This SOP describes the various steps the CHH IRB follows to review various types of protocol submissions, the types of decision and action taken as well as the necessary documentation to record its proceedings.

3. Responsibility

It is the responsibility of the CHH IRB Chair to preside over the meeting and exercise leadership to enable the IRB members and IRB Staff to fulfill their designated roles in the review of protocol-related documents submitted to the IRB in an efficient and effective manner. It is the responsibility of the Member Secretary to ensure that quorum will be met, that the required documents needed are available, to supervise the staff taking real time minutes of the proceedings and to report the results of expedited review.

It is the responsibility of the CHH IRB Chair/Member Secretary to moderate the meeting such that only one (1) member speaks at a time to facilitate clear documentation of proceeding.

It is the responsibility of CHH IRB Members to prepare and participate in IRB full board meetings to enable the IRB to conduct good reviews and take appropriate action related to the documents submitted to the IRB.

It is the responsibility of the CHH IRB Staff to prepare and make available all documents needed during the meeting and to take down minutes of the proceeding.

4. Workflow

ACTIVITY	PERSON/S RESPONSIBLE
Step 1: Call the Meeting to order	CHH IRB Chair
Step 2: Determine Quorum	Member Secretary
Step 3: Declare Conflict of Interest	CHH IRB Members
Step 4: Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes	CHH IRB Members
Step 5: Approve or modify the agenda	CHH IRB Members
Step 6: Discuss and decide on protocols for initial review	Primary Reviewers/CHH IRB Members
Step 7: Decide on protocol document resubmission	Primary reviewers/CHH IRB Members
Step 8: Discuss and decide on major protocol amendments	Primary reviewers/CHH IRB Members
Step 9: Discuss and decide on progress reports for full board review	Primary Reviewers/CHH IRB Members
Step 10: Approve Final Reports	Primary Reviewers/ CHH IRB Members
Step 11: Discuss protocol deviation/violation report for appropriate action	Primary reviewers/CHH IRB Members
Step 12: Report On Site SAEs for appropriate action	Designated IRB Member CHH IRB Member
Step 13: Report expedited review results	Member secretary
Step 14: Report/Discuss other matters for full board action information	CHH IRB Chair/Member secretary CHH IRB Members
Step 15: Formally close the Full Board Meeting	CHH IRB Chair

5. Procedures

Step 1- Call the Meeting to order: The Chair declares the formal opening of the Meeting at the appointed time and place once the majority of the members are present.

Step 2- Determine Quorum: The Member Secretary checks and reports if the quorum requirements are met to enable the meeting to start. IRB Quorum requirements should comply with national and international requirements and as defined in these SOPs. Quorum should be maintained throughout the duration of the meeting when members are required to vote to arrive at a decision. The following should be met to constitute quorum in a full board meeting of IRB:

- presence of at least five (5) voting members
- presence of one (1) medical/scientific
- presence of one (1) non-medical/non-scientific member
- presence of non-affiliated member
- presence of at least one male and one female member

Step 3- Declare Conflict of Interest

- The Chair asks the IRB members to declare their conflict of interest (COI) related to any protocols to be discussed.
- The IRB members check the agenda and declare their COI related to any protocol to be reviewed. They should be asked to leave the room during the discussion of such protocols, unless they are asked to reply to questions for clarification. Quorum should be maintained when members with COI leave the room. They return to the room after the discussion of their protocol.

Step 4- Approve or modify the agenda: The Chair asks the Members to examine and approve the items in the provisional meeting agenda. CHH IRB members may suggest additional items for discussion and the meeting agenda may be modified to include additional items for discussion.

Step 5- Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes: The Minutes of the previous meeting should have been sent to all members before the meeting for comments. The Chair asks the members to approve the Minutes of the last meeting and ask the members to voice out their comments, if any. The Chair also asks the members to comment on issues arising from the Minutes, and the discussions are recorded in the current Minutes by the Secretariat.

Step 6- Discuss and decide on protocols for initial review: The list of protocols for initial review are discussed according to the following procedures:

- The primary medical reviewer summarizes the protocol to enable the members to understand it.
- He/she uses the assessment form to comment on the technical and ethical issues in the protocol and makes recommendations about clarification, modification or approval. He/she also comments on the qualifications of the researchers and the sites.
- The Chair opens the protocol for discussion of IRB members taking note of additional and contradictory comments.
- If necessary, while the CHH IRB meeting is in progress, the PI may be contacted immediately (by telephone, cellphone, etc.) to answer questions and clarify certain protocol-related matters. If the questions/clarifications cannot be satisfactorily answered by these means, the IRB may invite the PI to personally attend the next full board meeting. The PI, however, will be allowed to enter the room and join only that part of the meeting that concerns his/her protocol, after which he/she will be asked to exit.
- The Chair summarizes the points raised and notes different views among members that should be resolved. The Chair asks the members to vote based on the decision points in the SOPs:
    - Approval (no further revision of the documents is required)
    - Minor Modification
    - Major Modification
    - Disapproval

- The Non-Medical / Non Scientific Reviewer presents his/her assessment of the Patient Information Sheet and Informed Consent Form making use of the ICF Assessment Form. The comments should note the discrepancies between the protocol and the information sheet, the correct informed consent or assent enclosed, and the provisions for proper signatures in the form.
- The Chair/Member Secretary summarizes consensus points after the discussion, takes note of voting results, articulates and records voting results and includes them in the Minutes of the meeting.
- The Chairman/Member secretary should moderate the meeting such that only one person is speaking at a time.
- Once the protocol documents are approved, the CHH IRB should agree on the frequency of continuing review.

Step 7- Decide on protocol document resubmission or Major Modification

- The Secretariat includes in the Meeting Agenda resubmissions required for Major Modification for full board discussion.
- The Primary Reviewers checked if the researchers complied with the CHH IRB requirements and recommended the appropriate decision. The CHH IRB members vote to approve the resubmission.
- The Chair/Member Secretary summarizes consensus points after the discussion, takes note of voting results, articulates and records voting results and includes them in the Minutes of the meeting.

Step 8- Discuss and decide on Major Protocol Amendments

- The Member Secretary screens amendments to determine Major Protocol Amendments that require full board review and to ensure inclusion in the Meeting Agenda.
- The Primary Reviewers review the amendment and present their assessment to the full board.
- The CHH IRB members vote to approve the Major Amendment.
- The Chair/Member Secretary summarizes consensus points after the discussion, takes note of voting results, articulates and records voting results and includes them in the Minutes of the meeting.

Step 9- Discuss and decide on Progress Reports for full board review

- The CHH IRB Staff/Member Secretary Screens Progress Reports that require full board review to ensure inclusion in the Meeting Agenda.
- The Primary Reviewers Review Progress Reports and present their assessment to the full board.
- The CHH IRB members vote to approve the Progress Reports.

Step 10- Approve Final Reports

- The CHH IRB Staff submits a list of Final Reports to full board review and includes them in the Meeting Agenda.
- The Primary Reviewers review Final Reports and present their assessment to the full board.
- The CHH IRB members vote to approve the Final Reports.
- The Chair/Member Secretary summarizes consensus points after the discussion, takes note of voting results, articulates and records voting results and includes them in the Minutes of the meeting.

Step 11- Discuss Protocol Deviation/ Violation Reports for appropriate action

- The CHH IRB Staff includes all Protocol Deviation / Violation Reports in the Meeting Agenda.
- The Primary Reviewers review the Reports and present their assessment and recommendation for appropriate action to the full board.
- The CHH IRB members vote to take corresponding action on the Protocol Deviation / Violation Reports.

Step 12-Report Onsite SAEs for appropriate action

- The CHH IRB Staff prepares a list of Onsite SAEs / SUSARs and submits them to the full board for appropriate action.
- The Designated CHH IRB Reviewers review the Onsite SAE/SUSAR Reports and present their assessment and recommendation for appropriate action to the full board.
- The CHH IRB members vote to take corresponding action on the Onsite SAE/ SUSAR Reports.

- The Chair/Member Secretary summarizes consensus points after the discussion, takes note of voting results, articulates and records voting results and includes them in the Minutes of the meeting.

Step 13- Report Expedited Review results: The CHH IRB Staff prepares a list of all Expedited Review results approved by the Member Secretary and submits them to the full board to inform the IRB members. CHH IRB Members may comment on the Report.

Step 14- Report/Discuss other matters for full board action/ information

- The Chair/Member-Secretary or any IRB Members may suggest items or other matters for the information of or discussion by full board.
- The Chair/Member-Secretary or any IRB Members may report queries and complaints that may need board discussion for appropriate action.

Step 15-Formally close the Full Board Meeting: The Chair formally closes the full board meeting after determination that all the Meeting Agenda items have been discussed.

6. History of SOP

Version No.	Date	Authors	Main change
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	02 October 2017	Dr. Elaine L. Gallardo	First Draft
7	04 January 2021	Dr. Elaine L. Gallardo	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	Atty. Dean G. Decal	No Change

7. References

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