1. Purpose

To describe procedures for the preparation and approval of the minutes of the Chong Hua Hospital Institutional Review Board (CHH IRB) full board meeting.

2. Scope

This SOP provides instructions related to the preparation of the CHH IRB full board meeting minutes and its approval by the IRB members.

3. Responsibility

It is the responsibility of the Secretariat, composed of the CHH IRB Staff under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the IRB meeting agenda.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Prepare template of Minutes of Meeting	CHH IRB Secretariat	7 days
Step 2: Preparation/Correction/Finalize of minutes of the meeting	CHH IRB Secretariat	7 days
Step 3: Approve minutes of the meeting	CHH IRB Members	During the Full Board Meeting
Step 4: File minutes of the meeting	CHH IRB Staff	During the Full Board Meeting

5. Procedures

Step 1- Prepare template of Minutes of Meeting

- The CHH IRB Staff fills up the basic information about each protocol submission for review of the IRB Meeting Minutes template with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.
- CHH IRB Secretariat uses this prepared template to document the proceedings during the full board meeting.

Step 2-Prepare minutes of the meeting

- As the CHH IRB meeting proceeds, the CHH IRB Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the CHH IRB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the CHH IRB Chair/Presiding Officer.
- The CHH IRB decisions and recommendations are collective in nature. No attribution to specific CHH IRB members is stated in the minutes.
- The meeting minutes should include the following items:
    - Date and venue of the meeting
    - Member attendance
    - Attendance of Researchers/PI, Independent Consultant and guest or observer, if any
    - Presiding Officer
    - Time when the meeting was called to order
    - Status of quorum at the start of the meeting and before every decision making
    - Members who declared COI and the protocol concerned
    - Discussion of items based on the order in meeting agenda
    - Summary of technical and ethical discussion points and recommendations
    - CHH IRB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.
    - If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress report is determined.

- If the review decision is disapproved, the reasons for the disapproval are stated.

- If the review decision (for initial and continuing reviews) is "for modification", the items to be revised are identified and the type of review for the resubmission is defined.
    - Attach the list of submissions approved through expedited review for the information of CHH IRB members.
    - Name and signature of the person who prepared the minutes
    - Name and signature of the Member-Secretary to indicate that contents have been verified and corrected
    - Name and signature of the Chair who approved the minutes with the date of approval

- The CHH IRB Staff who prepared the draft of the Meeting Minutes submits it to the Member-Secretary for correction and finalization within 7 days from the date of the meeting.
- The CHH IRB Staff group-e-mails the copy of the provisional meeting minutes to the CHH IRB Members for their review and comments within 7 days from the meeting date. The CHH IRB Members are expected to email their corrections to the group.
- The CHH IRB Secretariat finalizes minutes of the meeting incorporating corrections from the CHH IRB Members.
- The CHH IRB Staff distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next IRB meeting.

Step 3- Approve minutes of the meeting

- During the next full board meeting, the Chair asks the members to approve the Minutes.
- The CHH IRB members may suggest further corrections.
- The CHH IRB members approve the Minutes.
- The Chair signs approval after the meeting.

Step 4- File minutes of the meeting

- The CHH IRB Staff files approved meeting minutes in the folder for Meeting Minutes.
- Excerpts of meeting minutes may be extracted and filed in the specific protocol file folder, and the protocol file index is updated.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Dr. Cheryl K. Bullo	First draft
2	01 January 2014	Dr. Cheryl K. Bullo	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 CHH IRB Minutes
5	01 January 2017	Dr. Cheryl K. Bullo	Revised CHH IRB SOP from Version 04 to Version 05
6	02 October 2017	Dr. Elaine L. Gallardo	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP Ver02 template Revised CHH IRB Minutes format
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