	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD CHH IRB	
Version No: 09 Date of Approval: 08/21/24 Date of Effectivity: 08/21/24	**SOP 3.1 REVIEW OF AMENDMENTS**	

1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) review procedure for amendments of the protocol and related documents.

2. Scope

This SOP applies to previously approved study protocols and related documents that are being amended later and submitted for approval to the CHH IRB. Any amendment of the study related documents may not be implemented until reviewed and approved by the CHH IRB.

3. Responsibility

It is the responsibility of the IRB Secretariat to manage protocol amendment packages submitted by the PI.

It is the responsibility of the original primary reviewers to review the amendments and recommend appropriate action.

It is the responsibility of the CHH IRB Chair to determine whether the amendment goes to expedited or full committee review. The CHH IRB approves the final decision for amendments submitted by the PI to the CHH IRB.

4. Flowchart and Timelines

ACTIVITY	Turn around Time	PERSON(S) RESPONSIBLE
Step 1: Manage the Amendment Package	Day 0 (same day)	IRB Secretariat
Step 2: Notification of CHH IRB Chairperson	Day 1	IRB Secretariat
Step 3: Determine whether Expedited or Full Review & identify Primary Reviewers	Day 3	Chairperson
Step 4: Forward Amendment Package to Primary Reviewers	Day 3	IRB Secretariat
Step 5: Discuss the amendment or report the review result to the IRB during full board meeting Full Review by the CHH IRB	For expedited review: Day 17 (two weeks) For Full Board: as per submission timelines for regular Full Board Meeting	Primary Reviewer
Step 6: Notification to the Principal Investigator	Day 28 (four weeks)	IRB Secretariat
Step 7: File documents & update protocol file index and the Database	Day 28	IRB Secretariat

5. Procedures

Step 1- Manage the Amendment Package.

- The CHH IRB should properly inform the principal investigator to submit an application for amendment whenever there is any change regarding the composition of the study team, the study site, the protocol and related documents that it previously approved using the Protocol Amendment Submission Form
- Upon receipt of the protocol amendment package, the IRB Secretariat should follow the receiving procedure in SOP on the Management of Protocol Submission and SOP

on Procedure for Maintaining Confidentiality of IRB Documents. Contents of the Amendment Package should include but may not be limited to the ff.

- **Request for Amendment Memorandum :** The Principal Investigator, on an existing and previously approved protocol should:

  - State and describe the amendment
  - Provide the reason for the amendment if applicable
  - State any untoward effects with original protocol if applicable
  - State expected untoward effects because of the amendment if applicable

- **Protocol Amendment Submission Evaluation Form:** Check for completeness and for the presence of the required signatures (Principal Investigator or Medical Advisor of the Institute, if applicable). Form 2023-3.1-HRP-IRB ver08.1-PROTOCOL AMENDMENT EVALUATION SUBMISSION FORM
- **Protocol and Related Documents**
  - The related amendments may be summarized accordingly
  - The amended version of the protocol and related documents should be provided.
  - The changes or modifications should be underlined or highlighted.
  - CHH IRB Staff verifies whether the IRB Reference No. and forms used are correct.
  - The CHH IRB Staff records the submission in the protocol database

Step 3: Notification of CHH IRB Chairperson

- Upon receipt of the amendment package, the Secretariat should inform the Chairperson of the IRB verbally.
- The request for amendment memorandum and the protocol and related documents must be noted “received by the Chairperson” by the Secretariat.
- After review of the materials, the Chairperson will determine whether the protocol requires expedited or full review.
- The type of review will be noted on the comments portion of page 2 of the **Protocol Amendment Submission Form**

- If the Chairperson decides the protocol requires full board approval, the Chairperson will indicate this decision on the **Protocol Amendment Submission Form**
- For full board review, the following documents are distributed to primary reviewers:
    - The amendment's revision documents to clearly identify each change.
    - Requested changes to the consent form, if applicable
- The Secretariat places the protocol amendment request on the agenda for the next convened meeting.

Step 3- Determine whether expedited or full board review

CHH IRB Chair/Member Secretary reviews documents to determine whether amendment merits expedited or full review. Minor protocol amendments are those which are unlikely to compromise the integrity of the research or the welfare and rights of the participants and present no new ethical issues; and changes that are administrative in nature can be expedited. Some of the types of amendments are listed below.

- Modification of treatment – addition or reduction of treatments
- Any changes in inclusion/exclusion criteria
- Change in study design
- Additional treatment/s or the deletion of treatment/s
- Change in method of dosage formulation, such as, oral to intravenous
- Significant change in the number of subjects
- Increase: if there are <20 subjects enrolled, change of 5 is significant; if there are >20 subjects enrolled, a change of 20% is significant
- Decrease: if the decrease in the number of subjects alters the fundamental characteristics of the study, it is significant
- Significant decrease or increase in dosage amount
- Any other changes that will entail more than minimal risk.

Step 4: Forward amendment package to primary reviewers

- CHH IRB Staff identifies the Primary Reviewers who did the initial review and verifies IRB approval of the initial protocol submission.
- If Primary Reviewers are not available to do the review, CHH IRB Chair and/or Member-Secretary do the review provided they do not have COI. Otherwise the Chair designates qualified members to do the review.
- CHH IRB Staff prepares protocol amendment package; photocopies relevant documents of previous review/s of the protocol that will provide the Primary Reviewers with background information that will facilitate the assessment of the proposed amendment/s.
- CHH IRB Staff records the protocol amendment package in the Log of Disseminated IRB Review Materials.
- CHH IRB Staff sends the protocol amendment package and relevant documents of previous review/s with the Notice of Review to the Primary Reviewer/s at least 10 days before the full board meeting.

Review of Amendments

- The Primary Reviewers should review the pertinent documents in the protocol file and determine whether the proposed changes in the protocol will cause a change in the risk-benefit ratio of the approved protocol.
- The Primary Reviewer or his/her alternate reviews the amended documents and compares them with the previously IRB-approved documents in the protocol file folder to assess if the proposed amendment/s would alter the risk/benefit ratio, and/or would need reconsenting or communicating the change/s to participants. The Primary Reviewer may make appropriate recommendations using the IRB-part of Protocol Amendment Submission Form.
- Major protocol amendments are reviewed by full board while minor protocol amendments are reviewed by expedited review by the Primary Reviewers/Chair/Member-Secretary.

Step 5- Discuss the amendment or report the review result to the IRB during full board meeting

- The Primary Reviewer or his/her alternate presents the results of the review to the IRB during a full committee meeting.
- The CHH IRB decides whether or not there is a need for the PI to clarify, elaborate or explain further the amendment/s. The following are possible decisions of of the Board that are deemed major changes:
    - Approval
    - Request Further action
    - Request Further information/modification
    - Reconsenting of participants, and communicating the change to them
    - Disapproval
- The Primary Reviewer or his/her alternate submits the results of the review using the for-IRB portion of the Application Form for Amendment. The review decision is reported to the IRB during the full committee meeting.

Step 6- Communicate IRB decision to PI

- Refer to SOP on Communicating IRB Decision to PI
- CHH IRB Staff prepares Notification of IRB Decision/Approval for Protocol Amendment, for signature of CHH IRB Chair.
- If the amendment is approved, the PI is requested to submit an amended copy of the study protocol or protocol related document with an updated version no. and date.
- CHH IRB Staff sends the notification to the PI.

Step 7- File documents & update protocol file index and the protocol database

- CHH IRB Staff ensures that the version no. and date marked on the amended document are correct.

- CHH IRB Staff stamps the amended protocol or protocol-related document "Approved" with the approval date.
- CHH IRB Staff keeps a copy of all protocol amendment related documents in the protocol file folder and updates the protocol file index.

6. History of SOP

Version No.	Date	Authors	Main change
1	10 Sep 2010	Atty. Dean G. Decal	First Draft
2	01 Jan 2014	Dr. Manuel Emerson S. Donaldo	Change in the logo from CHH to CHH IRB logo Revised SOP and form numbering
3	01 Sep 2014	Dr. Manuel Emerson S. Donaldo	Change of IRB SOP in accordance to PHREB SOP Format
4	01 Oct 2014	Dr. Manuel Emerson S. Donaldo	Revised IRB SOP in accordance to PHREB SOP Format
5	01 Jan 2017	Dr. Manuel Emerson S. Donaldo	Revised CHH IRB SOP from Version 04 to Version 05
6	02 Oct 2017	Dr. Manuel Emerson S. Donaldo	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template Revised CHH IRB Protocol Amendment Submission Form
7	04 Jan 2021	Dr. Manuel Emerson S. Donaldo	No change
8	04 January 2024	Atty. Dean G. Decal	Revised CHH IRB SOP due to re-accreditation and survey
9	25 August 2024	Dr. Maria Teresa Cañete	Revisions to include removing wording "Major Amendment" or "Minor Minor Amendment, " Additional timelines, provision of Reconsenting as decision of major change in protocol

7. References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- Code of Federal Regulation (CFR), 21 §56.110, The United States of America, 1998
- Relevant SOPs: SOP/006/02, 007, 008 and 009
- National Ethical Guidelines for Health Research 2011 PNHRS
- 2017 Department of Health – SOP Version No. 2