1. Purpose

To describe the procedures of Chong Hua Hospital Institutional Review Board (CHH IRB) when the protocol resubmissions are received for review.

2. Scope

This SOP applies to the IRB review and approval of study protocols recommended for minor or major modifications during initial and continuing review.

3. Responsibility

It is the responsibility of the CHH IRB Chair/ Secretariat to classify resubmitted protocols for expedited or full board review.

It is the responsibility of primary reviewers to review the resubmitted documents to determine if they have complied with the required modifications before granting approval during expedited review or to recommend approval of protocols with major modification to full board.

It is the responsibility of IRB members to approve resubmitted protocols with major modification after discussion.

4. Flowchart

ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
Step 1: Receive the resubmitted protocol package from the PI	CHH IRB Staff	14 days
Step 2: Send the protocol package to the primary reviewers.	CHH IRB Staff	
Step 3: Review if the resubmission complied with the required modification	Primary Reviewers	
Step 4: Return the documents with a decision after expedited review or recommended a decision to full board	Primary Reviewers	
Step 5: Discuss and decide on major modifications received during a full board meeting	IRB Members	Full Board Review
Step 6: Accomplish the proforma of Letter of Approval and communicate the IRB decision to the PI	CHH IRB Staff	14 days
Step 7: File copies of the documents in the protocol file folder and update the protocol database	CHH IRB Staff	

5. Procedures

Step 1- Receive the resubmitted protocol package: The PI will use the protocol resubmission form when submitting the documents. The CHH IRB staff receives the resubmitted protocol documents from the PI.

Step 2- Send the protocol package to the primary reviewers: The CHH IRB staff sends the package to the primary reviewers during initial review. The CHH IRB staff logs the protocol documents in the Log of Disseminated IRB Review Materials.

Step 3- Review if the resubmission complied with the required modification: The Chair/Member-Secretary or designated primary reviewers may review minor protocol modifications. The primary reviewers review the resubmitted documents and compare them with the requirements for modification.

Step 4- Return the documents with a decision after expedited review or recommend a decision to full board

- The primary reviewers return the resubmission package indicating their decision.
- In expedited review, the primary reviewers approve the resubmitted documents if the PI has substantially complied with the required modifications.
- Minor modifications recommended by the full board should also go to expedited review.
- For major modifications for full board discussion, the primary reviewers recommend approval.

Step 5-Discuss and decide on major modifications received during a full board meeting: Primary reviewers resend their assessment of major modifications during full board discussion and make a recommendation for approval. CHH IRB members vote to endorse or not to endorse the recommendation for approval.

Step 6- Accomplish the Proforma of Letter of Approval and communicate the IRB decision to the PI: For approved resubmitted protocols, the CHH IRB staff prepares the Proforma of Letter of Approval that the Chair should sign. The CHH IRB decision is communicated to the PI within four (4) weeks from resubmission.

Step 7- 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	10 September 2010	Att. Dean G. Decal	First Draft
2	01 January 2014	Rev. Fr. Benedicto P. Tao	Change in the logo from CHH to CHH IRB logo Revised SOP and Form numbering
3	-	-	-
4	-	-	-
5	-	-	-
6	02 October 2017	Rev. Fr. Benedicto P. Tao	Revised CHH IRB SOP in accordance to 2017 DOH-REC SIO ver02 Template
7	05 January 2021	Atty. Dean G. Decal	No change
8	31 August 2023	Atty. Dean G. Decal	Revised CHH IRB SOP due to PHREB-FERCAP re-accreditation and survey
9	21 August 2024	Atty. Dean G. Decal	No Change

7. References

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