1. Purpose

To describe the procedure for communicating the Chong Hua Hospital Institutional Review Board (CHH IRB) decision to the PI.

2. Scope

This SOP provides instructions related to the preparation of the CHH IRB communication to the PI and the management of such documents.

3. Responsibility

It is the responsibility of the CHH IRB Secretariat to prepare the Approval or Notification Letter to the PI to be signed by the CHH IRB Chair.

4. Flowchart

Activity	Person/ Responsible	Timeline
Step 1: Prepare Notification/Approval Letter to PI	CHH IRB secretariat, Chair	14 Days from Receipt of Protocol
Step 2: Send notification/Approval letter to PI	CHH IRB staff	7 Days
Step 3: File Notification/Approval to PI	CHH IRB staff	7 Days
Step 4: Update Protocol Database	CHH IRB staff	7 Days

5. Procedure

Step 1- Prepare Notification / Approval Letter to PI

- Based on the final version of the Meeting Minutes, the CHH IRB Staff prepares the IRB communication to the PI in duplicate copies using the standard SOP template.
- For the Notification Letter, the CHH IRB Staff copies the list of recommendations from the meeting minutes to communicate them to the PI.
- The CHH IRB Chair signs and dates the Notification / Approval Letter.
- All Notifications / Approval Letters should be ready within 7 calendar days after the meeting date for full board or 7 calendar days after receipt of expedited review results.

Step 2- Send Notification / Approval Letter to PI

- The CHH IRB Staff informs the PI/Research Assistant that the original copy of the Notification or Approval Letter is ready for pick-up.
- The CHH IRB Staff emails a scanned copy of the Notification / Approval Letter to the PI.
- The CHH IRB Staff logs the Notification / Approval in the Log of Outgoing Document when the original copies are released.

Step 3- File Notification /Approval Letter to PI: The CHH IRB Staff files a duplicate copy of the Notification/ Approval Certificate in the protocol file folder and updates the Protocol File Index.

Step 4- Update protocol database: The CHH IRB Staff updates the protocol database.

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. Cheryl K. Bullo	Change of IRB SOP in accordance to PHREB SOP Format Revised SOP title from "Communication records" to communicating IRB/Decision/Incoming/outgoing Communications"
4	01 October 2014	Dr. Cheryl K. Bullo	Revised IRB SOP in accordance to PHREB SOP Format
5	01 January 2017	Dr. Cheryl K. Bullo	Revised CHH IRB SOP from Version 04 to version 05
6	02 October 2017	Dr. Cheryl K. Bullo	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template Revised SOP title from "Communication records" to communicating IRB/Decision/Incoming/outgoing Communications"
7	04 January 2021	Dr. Cheryl K. Bullo	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	04 January 2024	Atty. Dean G. Decal	No Change

7. Reference

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