## 1.Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to early termination of protocol implementation.

## 2. Scope

This procedure describes how the CHH IRB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data safety monitoring board (DSMB), the Scientific Director, sponsor, PI, By the IRB itself or other authorized bodies.

## 3. Responsibility

It is the responsibility of the CHH IRB to act on any early protocol termination application. It is also the responsibility of the CHH IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at full committee for appropriate action.

The CHH IRB Secretariat is responsible for the receipt and management of the termination documentation. The primary reviewers review the reasons for early termination and make a recommendation to full committee.

## 4. Flowchart

| ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|---|---|---|
| **Step 1:** Receive application for early study termination | CHH IRB Staff | 7 days |
| **Step 2:**Refer Notice of Early Termination to Primary Reviewers | CHH IRB Chair/Member Secretary, primary reviewer | |
| **Step 3:** Review the submission | CHH IRB Members | During full board meeting |
| **Step 4:** Deliberate decision during full board meeting | CHH IRB Members | |
| **Step 4:** Communicate IRB's response | CHH IRB Staff/Chair | 14 days |
| **Step 5:** File pertinent documents and update database | CHH IRB Staff | |

## 5. Procedures

### Step 1- Receive application or recommendation for early study termination

- An application for early termination is submitted when a CHH IRB-approved study protocol is being recommended for termination before its scheduled completion. This is done when the rights, safety and welfare of participants are threatened or upon the request of the PI or sponsor due to operational problems.
- Recommendation for early termination may come from the Sponsor, DSMB, Scientific Director, CHH IRB members, or other authorized bodies.
- CHH IRB Staff receives the study protocol termination package prepared and submitted by the principal investigator and verifies whether the IRB Reference Number and form used are correct, and the completeness of the Early Study Termination Form.
- Check approval given by the CHH IRB and type of review from the protocol database.

**Step 2- Forward Notice of Early Termination to Primary Reviewers-** CHH IRB Staff forwards the document package to the Primary Reviewer/s.

**Step 3- Review the submission**

- Assess the termination issues and make recommendation. The primary reviewers review the safety data during the full board meeting. It is important for the termination package to contain a plan to follow up the participants who are still active in the study.
- For submission to full board review, the CHH IRB Secretariat includes the review of the study for early termination in the meeting agenda.

**Step 4- Discuss decision during full committee meeting-** The CHH IRB deliberates on the effects of the early study termination on the safety and welfare of study participants.

Final decision of the application are as follows:

  - Approval
  - Acknowledgment
  - Further information required

**Step 5- Communicate IRB decision to PI**- Based on the minutes of the meeting, the CHH IRB Staff prepares the Notification Letter – Early Study Termination for signature of the CHH IRB Chair. The PI may be requested to provide additional information or documents or implement actions to ensure the safety and welfare of subjects still active in the study.

**Step 6- File pertinent documents and update protocol database**

- The CHH IRB Staff files the Early Termination Report, excerpts of the minutes of the meeting when the report was discussed and the Notification Letter (including the response from the PI, if any) in the protocol file folder and updates the protocol file index.
- Upon approval of the Early Study Termination application, the study protocol is classified as inactive, the IRB Reference No. is updated and the protocol file folder re-labeled and transferred to the storage cabinet for inactive files.
- CHH IRB Staff updates the protocol database and labels the protocol “inactive-early termination”.

**6. History of SOP**

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 10 September 2010 | Mr. Romel V. Cabazor | First Draft |
| 2 | 01 January 2014 | Rev. Fr. Benedicto P. Tao | Change in the logo from CHH to CHH IRB logo<br><br>Revised SOP, Form numbering and Request Record Form |
| 3 | 01 September 2014 | Rev. Fr. Benedicto P. Tao | Change of irb SOP in accordance to PRHEB SOP Format |
| 4 | 01 October 2014 | Rev. Fr. Benedicto P. Tao | Revised IRB in accordance to PHREB SOP Format |
| 5 | 01 January 2017 | Atty. Dean G. Decal | Revised CHH IRB SOP from version 04 to version 05 |
| 6 | 02 October 2017 | Dr. Manuel Emerson S. Donaldo | Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template<br><br>Revised CHH IRB Query/Complaint Record Form |
| 7 | 04 January 2021 | Dr. Manuel Emerson S. Donaldo | No change |
| 8 | 04 January 2024 | Dr. Manuel Emerson S. Donaldo | No change |
| 9 | 21 August 2024 | Dr. Manuel Emerson S. Donaldo | No change |

**7. References**


- 2017 Department of Health-SOP Version No.2