1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) review procedures for final reports.

2. Scope

This SOP provides instructions for the review of final reports that are required by the CHH IRB to be submitted by the principal investigator when the approved study is completed or when the study site is closed. The final report when approved by the CHH IRB becomes the basis for initiation of the archiving procedure. This SOP applies to the review of final/closure report of a study protocol approved by the CHH IRB.

3. Responsibility

It is the responsibility of the CHH IRB Staff to identify study protocols whose final reports are due.

It is the responsibility of the CHH IRB secretariat to review the report for completeness before making copies for the Board meeting.

It is the responsibility of the Primary Reviewers to review the reports to check completeness of information and to ensure that the data are in accordance with the protocol and other related documents approved by the CHH IRB.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Determination of protocol due date for final report	CHH IRB Staff	Review of final report should take place within 14 days except when there is a delay in the due to the schedule of the full board meeting
Step 2: Receive the closure report package and check its completeness	CHH IRB Staff	
Step 3: Identify primary reviewers	CHH IRB Chair/Secretary	
Step 4: Forward final/closure report to primary reviewers for review	CHH IRB Staff, Primary Reviewers	
Step 5: Discuss the final/closure report during IRB Full board meeting	Primary reviewers	
Step 6: Communicate IRB decisions to PI	CHH IRB Secretariat, Chair	
Step 7: File documents & update protocol file index and protocol database	CHH IRB Staff	
Step 8: Communicate archival action to PI using the Archival Notification form.	CHH IRB Staff	within 7 days after archiving

5. Procedures

Step 1- Determination of protocol due date for final report.

- The CHH IRB Staff checks the Study Protocol Database and tracks the due date of final reports of study protocols approved by CHH IRB at the end of the month.
- The CHH IRB Staff informs the respective PIs of study protocols whose ethical clearances have expired to submit a Final Report at least one month in advance of the due date of review.

Step 2- Receive the final/closure package and check its completeness: The submission shall include the accomplished Closure/Final Report forms. The CHH IRB Staff verifies the completeness of the submission and whether the IRB Reference No. and the forms used are correct.

Step 3- Identify primary reviewers: The CHH IRB Staff identifies the Primary Reviewers of the protocol from the protocol database. If the Primary Reviewer is not available, the review is done either by the CHH IRB Chair/Member-Secretary, or qualified Member/s designated by the Chair/Member-Secretary.

Step 4- Forward final/closure report to primary reviewers for review

- The CHH IRB Staff records the Closure/Final Report package together with the Notice of Review and a copy of the latest version of the protocol in the Log of Disseminated IRB Review Materials.
- The Closure/Final Report package is forwarded to the primary reviewer/s at least 7 days before the full board meeting.
- The Primary Reviewer/s accomplishes the review by commenting and recommending appropriate action on the Closure/Final Report form.
- Primary Reviewer signs and dates the form and returns the Closure/Final Report package to the CHH IRB Staff.

Step 5- Approve the final/closure report during full board meeting

- The Primary Reviewer presents the results of the review.
- The CHH IRB decision can be any of the following:
    - Acknowledged/Accepted
    - Request for further information, specify
    - Recommend further action, specify

Step 6- Communicate IRB decision to PI

- The Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required.
- The CHH IRB Staff prepares Notification of IRB Decision – Review of Closure/Final Report for signature of the CHH IRB Chair.
- The CHH IRB Staff sends the notification to the PI

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

- The CHH IRB Staff files the accomplished, signed and dated Closure/Final Report and other related documents in the protocol file folder and updates the protocol file index.
- Upon approval of the Closure/Final Report, the study protocol is classified as inactive, the IRB Reference No. is updated and the protocol file folder re-labeled and transferred to storage cabinet for inactive files.
- CHH IRB Staff updates the protocol database.

Step 8- Communicate archival action to PI: CHH IRB staff sends notification to the PI that the study protocol has been classified as inactive.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Atty. Dean G. Decal	First Draft
2	01 January 2014	Dr. Manuel Emerson S. Donaldo	Change in the logo from CHH to CHH IRB logo
3	01 September 2014	Dr. Manuel Emerson S. Donaldo	Change of IRB in accordance to PHREB SOP Format
4	01 September 2014	Dr. Manuel Emerson S. Donaldo	Revised IRB SOP in accordance to PHREB SOP Format
5	01 January 2017	Dr. Manuel Emerson S. Donaldo	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 Revised CHH IRB Closure/Final Report form
7	04 January 2021	Dr. Manuel Emerson S. Donaldo	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