1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) review procedures for Continuing Review report (CRR) and Review of Progress Report (PR) for renewal of CHH IRB approval.

The purpose of the CRR and the PR is to ensure compliance in the conduct of the study with the approved protocol and the continuous protection of the rights and welfare of research participants. Thus, the IRB maintains oversight over the research initially reviewed, as long as the research is ongoing.

Submission of this CRR is required one year from the approval of the protocol.

The purpose of Review of Progress Report is similar to Continuing review, but this report may be done anytime.

2. Scope

This SOP applies to the conduct of Continuing Review of study protocols still ongoing but whose ethical clearance is about to expire.

The CRR is an annual report that becomes the basis for continuing review of protocols, the approval of which needs to be renewed every year. Thus, submission is required 30 days before expiration of last approval.

Continuing review and Review of Progress report of the study should be conducted through a full board review procedure except when:

- The study was eligible for and initially reviewed by an expedited review procedure or
- The study has changed such that the only activities remaining are eligible for expedited review, ie: Study is Active, but Closed to Enrollment; Active, Data analysis Only; or Active, Long Term Follow-Up only

Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the CHH IRB may require more frequent submission of progress reports.

3. Responsibility

It is the responsibility of the CHH IRB Secretariat to remind the principal investigators to submit the application for continuing review and/or progress reports one month before the end of the study or one month before the due date of the submission of progress report.

It is also the responsibility of the CHH IRB Secretariat to forward the reports to the primary reviewers for review, and to communicate IRB decisions to the PI.

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

The CHH IRB is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol informed consent documents and assent documents are examined to ensure that the information remains accurate.

4. Flow chart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Receive the application for continuing review or the progress package and check its completeness	CHH IRB Secretariat	Review of application of continuing review or protocol progress reports should be completed within 14 days when done through expedited review. It may take longer for full board review depending on the schedule of the full board meeting.
Step 2: Determine type of review & identify primary reviewers	CHH IRB Secretariat	
Step 3: Forward the application for continuing review or the progress report to primary reviewers	CHH IRB Secretariat	
Step 4: Discuss the progress report or report expedited review results to the IRB during full board meeting	CHH IRB Secretariat, Members and Chairperson	
Step 5: Communicate IRB decision to PI	CHH IRB Secretariat	7 Days
Step 6: File document & Update protocol file index and protocol database	CHH IRB Secretariat	

5. Procedures

Step 1- Receive the progress report package and check its completeness

- The CHH IRB Staff periodically checks the protocol database to track due dates of progress reports of study protocols approved by the CHH IRB.
- The CHH IRB Staff prepares and sends reminder letter addressed to the PI one month before the due date of the report.
- For studies of long term duration (more than 3 years), the PI and the rest of the study team are required to submit evidence of updated Good Clinical Practice (GCP) Training.
- The continuing review application package shall include the accomplished Progress Report Form (form 2023-HRP-IRB-018-CONTINUING REVIEW APPLICATION FORM) with the informed consent document currently in use. The CHH IRB Staff

checks the completeness of submitted application for review package using the IRB Reference No. and forms used are correct.

- The CHH IRB Staff records the submission in the logbook for received documents.

Step 2- Determine type of review & identify primary reviewers

- The continuing review of protocol initially reviewed at full board is again reviewed at full board.
- The CHH IRB Staff identifies the primary reviewers who did the initial review.
- If Primary Reviewers are not available to do the review, the CHH IRB Chair and/or Secretary may do the review provided they do not have COI. Otherwise the Chair designates qualified members to do the review.

Step 3- Forward progress report to primary reviewers for review

- CHH IRB Staff photocopies relevant documents of previous review/s of the protocol such as current versions of the protocol, informed consent forms (ICF), protocol amendments, protocol deviations and on-site SAEs/SUSARs since the last continuing review. They will provide the Primary Reviewer/s with background information to facilitate the assessment of risk-benefit ratio. Better still, the Primary Reviewers should go to the CHH IRB office to review pertinent documents in the protocol file folder and determine whether there is a change in the risk-benefit ratio.
- The CHH IRB Staff sends the Progress Report package to the primary reviewers at least 7 days before a full-board meeting.
- Primary reviewers conduct a continuing review of progress/annual report if they are in accordance with the protocol and related documents approved by the CHH IRB.
- Primary reviewers refer to documents in the protocol file folder to check compliance with the latest CHH IRB-approved protocol and ICF.

- **Key Evaluation Points:** In the review of the progress/annual report, the following are the key evaluation points:

- **Risk Assessment**

  - The risks to the subjects are minimized

- The risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to be gained from the study.

- **Adequacy of Informed Consent**
  - Informed consent/Assent forms current (most recent)
  - Appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)

- **Local Issues**
  - Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials.
  - Evaluation, investigation and resolution of complaints related to the research, if any Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.)
  - Report from third party observation of the research (including the informed consent process) carried out
  - Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies), if any.

- **Trial Progress**
  - Start date of the study and expected duration
  - Total subject enrollment
  - Expected enrollment
  - Actual enrollment
  - Enrollment issues

- Subject withdrawal
  - Number of subjects who withdrew
  - Lost to follow-up
- Summary of reasons for withdrawal at local site

- The CHH IRB may also request the Principal Investigator to provide additional information, when necessary.
- The Primary Reviewer/s must complete the review within 7 days prior to the IRB meeting.

Step 4- Discuss the progress report or report expedited review results to the IRB during full board meeting

For full board review of progress report:

- The CHH IRB Secretariat collates the comments of the Primary Reviewers and includes the application for renewal of IRB approval in the agenda.
- The protocol file folder for continuing review, including relevant CHH IRB meeting minutes, should be made available during the meeting.
- During the meeting, the Primary Reviewers present a summary of the progress of the research, any significant issues and their recommendation to full-board.
- The CHH IRB members determine the need for the investigator to elaborate, explain or clarify any aspect of the progress/annual report as deemed necessary.
- **IRB Decisions for Continuing Review**: The following are the possible IRB decisions for continuing review:
  - Renew approval
  - Request additional information
  - Recommend modification
  - Suspend:
    - Enrollment of new subjects
    - Research procedures in currently enrolled subjects
    - Entire study

- Disapprove renewal

- Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting by the Chair/Member-Secretary.

Step 5- Communicate IRB decision to PI

- The CHH IRB 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.
- CHH IRB Staff prepares Notification of IRB Decision – Progress/Annual Report for signature of CHH IRB Chair.
- CHH IRB Staff sends the notification to the PI

Step 6-File documents & update protocol file index and protocol database: CHH IRB Staff keeps the continuing review application package together with the review comments of the primary reviewer/s in the protocol file folder and updates the protocol file index. CHH IRB Staff then updates the protocol database.

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	-	-	-
4	-	-	-
5	01 January 2017	Dr. Manuel Emerson S. Donaldo	Revised CHH IRB SOP from version 04 to version 05 Inclusion of SOP on Continuing Review
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 Continuing Review Application form
7	04 January 2021	Dr. Manuel Emerson S. Donaldo	No change
8	04 January 2024	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