1. Purpose

To describe the procedure for writing and SOPs used by the Chong Hua Hospital Institutional Review Board (CHH IRB).

2. Scope

This SOP provides instructions on how the new CHH IRB SOPs are prepared.

3. Responsibility

It is the responsibility of the CHH IRB Chair to organize an SOP Team to formulate the SOPs of the CHH IRB.

The SOP Team is an ad hoc committee composed of designated CHH IRB members and invited resource persons. The team is responsible for drafting new SOPs and revising existing SOPs when necessary. The team must follow existing institutional procedures when drafting SOPs in consultation with the Secretariat and Chair. The team submits the draft SOPs to the Chair.

The Chair convenes an IRB meeting to review and finalize draft SOPs and submit the final draft to the Medical Director/COO for final approval.

The Secretariat is responsible for keeping all versions of SOPs and ensures that all CHH IRB members have access to current versions of SOPs to guide them in the performance of their functions.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE
Step 1: Organize an SOP Team	CHH IRB Chair
Step 2: Identify reference template with corresponding layout	CHH IRB SOP Team
Step 3: Draft new SOPs and submit to the chair	CHH IRB SOP Team
Step 4: Review and finalize new SOPs in an IRB meeting and submit to the Medical Director/COO	CHH IRB IRB Chair, IRB Members
Step 5: Approve and sign new SOPs	Medical Director/COO
Step 6: Distribute approved SOPs and keep copies in the IRB files	CHH IRB Secretariat

5. Procedures

Step 1- Organize an SOP Team

- The Chair assigns members to be part of the SOP Team, and invites resource person as needed.
- The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.
- The Chair may organize SOP Team workshops to facilitate the drafting of SOPs.

Step 2- Identify reference templates with corresponding layout: Identify reference templates with corresponding layout from SOPs of other IRBs to guide the SOP team in drafting new SOPs (see ANNEX I, CHH IRB SOP Template)

An IRB SOP have the following format:

a. SOP Number
b. Title
c. Table of Contents
d. Purpose of the SOP
e. Scope which defines the extent of coverage of the SOP and its limitations

f. Responsibility identifies the persons assigned to perform specific tasks
g. during SOP implementation
h. Flowchart/Steps
i. Procedures which elaborates the steps outlined in the process flow
j. History of SOP
k. References
l. Glossary
m. Standard forms and checklists to be used

An IRB SOP have the following format:

- Each SOP is given a number and a title that is self-explanatory and is easily understood.
- A unique code number with the format SOP/*XXX*/*VV* will be assigned to each SOP item by the *Chairman.*
- XXX is a three-digit number assigned specifically to the SOP.
- *VV* is a two-digit number identifying the version of the SOP.
- Each annex will be given a unique code number with the formatting provided by the Joint Commission International (JCI), which is HRP-IRB-*NNN*.
- HRP is the abbreviation for Human Subjects Research Programs; IRB is the abbreviation of the Department/Division which is the Institutional Review Board and NNN is the count for the number of forms.
- The SOP Document History describes the different versions of the document by version no., version date, and description of main changes. This is attached with the SOP Master file.

The typical SOP uses a header with the following elements:

- Institutional seal or logo
- Name of institution
- SOP identifier
- SOP title
- Effectivity date
- Page number

Step 3- Draft new SOPs and submit to the Chair: The CHH IRB SOPs should contain details under the following main topics:

- Introduction – contains a statement of ethical principles that will guide the CHH IRB
- Structure and Composition of the CHH IRB – describes the composition of CHH IRB membership with specific review functions
- Initial Review Procedures – describe types of review and initial review procedures
- Monitoring Procedures – describe how the CHH IRB monitor implementation of approved protocols
- Management of Meetings, Documentation and Archiving – describe administrative procedures that support the review functions
- Writing and Revising SOPs – describes how to draft and revise SOPs

The SOP Team submits completed SOP draft to the CHH IRB Chair.

Step 4- Review and finalize new SOPs in an IRB meeting and submit to the Medical Director/COO: The CHH IRB Chair presents the draft SOPs during an IRB meeting for the members to discuss and finalize the draft. CHH IRB Chair submits the approved draft to the Medical Director/COO for approval.

Step 5- Approve and sign new SOPs: The Medical Director/COO reviews and approves the SOPs by signing in the designated section. The approved SOPs will be implemented after approval by the Medical Director/COO.

Step 6-Distribute approved SOPs and keep copies in the CHH IRB files

- The CHH IRB Staff distributes the new IRB SOPs to all CHH IRB Members and Staff and files the original copy in the CHH IRB storage cabinet.
- The SOP Manual with downloadable forms are uploaded on the Chong Hua Hospital website for the use of and guidance of researchers.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Dr. Manuel Emerson S. Donaldo	First draft
2	01 January 2014	Dr. Manuel Emerson S. Donaldo	Change in the logo from CHH to CHH IRB logo Revised SOP and form numbering
3	01 September 2014	Dr. Manuel Emerson S. Donaldo	Change of IRB SOP in accordance to PHREB SOP format
4	01 October 2014	Dr. Manuel Emerson S. Donaldo	Revised IRB SOP 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	Atty. Dean G. Decal	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template Inclusion of history of SOP document revision per CHH IRB SOP
7	04 January 2021	Atty. Dean G. Decal	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. Reference

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