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1. Purpose

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the **Chong Hua Hospital Institutional Review Board (CHH IRB).** The SOPs developed in this SOP are adopted from the SOPs from FERCAP International.

The SOPs will provide clear, unambiguous instructions so that the related activities in the institutional review board are conducted in accordance with the WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, *National Guideline for Ethics Committees* and ICH (International Conferences on Harmonization) Good Clinical Practice (GCP)

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the **Chong Hua Hospital Institutional Review Board**

3. Responsibility

Chairperson of the CHH IRB:

- It is the responsibility of the chairman of CHH - IRB to appoint the members to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the hospital.
- Reviews and approves the SOPs
- Signs and dates when he receives the approved SOPs

Secretariat of IRB:

- Coordinates activities of writing, reviewing, distributing and amending SOPs
- Maintains on file all current SOPs and the list of SOP
- Maintains an up-to-date distribution list for each SOP distributed
- Distributes the SOPs with a receipt to all users
- Ensures all institutional review board members and involved administrative staff have access to the SOPs

- Ensures the institutional review board members and involved staff are working according to current version of SOPs

Institutional Review Board members and involved administrative staff:

- Sign and date when they receive the approved SOPs
- Maintain a file of all SOPs received
- Return all out-of-date SOPs to SOP Administrator

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Assign SOP to different members	Chairman
II	List all relevant SOPs	IRB members
III	Design a format and layout to adopt	IRB members
IV	Write and approve a new SOP /revised SOP	IRB members / Chairman
V	Implement and request for distribute and file all SOPs	Secretariat
VI	Review SOPs	IRB members/ administrative staff/chair person
VII	New SOP Training	Secretariat
VIII	Manage and archive superseded SOPs	Secretariat IRB members / Chairman

5. Detailed Instructions

5.1 Appoint the SOP Team

- The chairman appoints the appropriate individuals who have a thorough understanding of ethical review process to form the SOP writing team

5.2 List all relevant SOPs

- Determine the needed SOPs for the proper function of the CHH IRB
- Write down step by step all IRB procedures.
- Organize, divide and name each process.
- Make a list of SOPs with coding reference (ANNEX 1)

5.3 Coding SOPs

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.

5.4 Write and approve SOP

When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the CHH IRB by the chairman.

The draft SOP will be discussed with institutional review board members and all relevant administrative staff. The SOP should be agreed upon by the people involved in that particular task. The final version of the SOP will be submitted to the Chairperson for review and approval prior to the approval by the Medical Director/COO.

5.5 Implement, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
  - The approved SOPs will be distributed to the EC members and the relevant staff by the Secretariat. When revised version is distributed, the old version will be retrieved and destroyed. Only one copy of the superseded version will be retained in the CHH IRB office.
  - One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the institutional review board and keep the file in the *CHH – IRB office*.

5.6 Review and request for a revision of an existing SOP

- Any member of the ethics committee, secretariat or administrative staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in Annex 3 to make a request.
- If the Chairman agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the chairperson will inform the person who made the request of the decision.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs.
- The Board is expected to review and update the SOPs at least every *3* years.

5.7 Training on SOPs

- New SOPs are circulated for self reading to the members and the secretariat
- Training is documented in the training log sheet **(Refer to Annex 4)**

5.8 Manage and archive superseded SOPs

Superseded SOPs should be retained and clearly marked "superseded" and archived in the historical file by the Secretariat.

6. ANNEX 1: SOP Table of Contents ver05

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CHAPTER NO.	TOPICS/STANDARD OPERATING PROCEDURE (SOP)	SOP Code
1	**IRB Structure and Composition**	
	1.1 Ethical Framework and Constitution of the IRB	SOP/001/05
	1.2 Selection of Independent Consultants	SOP/002/05
	1.3 Training Personnel and Ethics Committee Members	SOP/003/05
	1.4 Confidentiality/Conflict of Interest Agreement	SOP/004/05
	1.5 Incentives for IRB Members and Consultants	SOP/005/05
2	**Types of Review**	
	2.1 Expedited Review	SOP/006/05
	2.2 Full Board Review	SOP/007/05
3	**Initial Review**	
	3.1 Management of Protocols Submissions	SOP/008/05
	3.2 Use of Study Assessment Form	SOP/009/05
	3.3 Review of Medical Device Study	SOP/010/05
4	**Continuing Review**	
	4.1 Review of Final Report	SOP/011/05
	4.2 Study Protocol Amendment	SOP/012/05
	4.3 Review of Serious Adverse Event (SAE) Reports	SOP/013/05
	4.4 Management of Protocol Deviation and Violation	SOP/014/05
	4.5 Management of Study Termination	SOP/015/05
	4.6 SOP on Protocol Continuing Review	SOP/016/05

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ANNEX 2: Standard Operating Procedures Template (page 1 of 4)

TITLE

SOP/ /

" "

Effective Date: _____
Supersedes: _____

Author: _____ Date: _____

Approved by: _____ Date: _____
Medical Director

ANNEX 2: Standard Operating Procedures Template (page 2 of 4)

chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD **Title:** __ _____	SOP/___/ __ **Effective date:** __ __ ____ **Page __ of __**

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ANNEX 2: Standard Operating Procedures Template (page 3 of 4)

chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD	SOP/___/__ Effective date: __ __ ____
	Title: __ _____	Page __ of __

1. **Purpose** - *summarizes and explains the objectives of the procedure.*

2. **Scope** - *states the range of activities that the SOP applies to.*

3. **Responsibility** - *refers to person(s) assigned to perform the activities involved in the SOP.*

4. **Flowchart** - *simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity.*

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		
II		
III		
IV		

ANNEX 2: Standard Operating Procedures Template (page 4 of 4)

chh_irb@chonghua.com.ph	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD Title: __ _____	SOP/___/ __ Effective date: __ __ ____ Page __ of __

5. **Detailed instructions** - *describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*

6. **ANNEX** - *documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.*

7. **Reference** - *lists sources of the information given in the SOP.*

ANNEX 3: Request for Revision of an SOP

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

REQUEST FOR REVISION OF AN SOP

Form HRP-IRB-003

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP #:	
SOP Title:	
Details of problems or deficiency in the SOP:	
Identified by:	Date (dd/mm/yyyy):
Discussed with:	
SOP revision required: ☐ Yes If Yes, to be carried out by whom? _____ ☐ No If No, why not? _____	
Date SOP re-finalized:	
Date SOP approved:	
Date SOP becomes effective:	

ANNEX 4: SOP Training Log Sheet

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

SOP TRAINING LOG SHEET

Form HRP-IRB-032

SOP:	Date of Training:	
VENUE:		
NAME	**DESIGNATION**	**SIGNATURE**
1)		
2)		
3)		
4)		
5)		
6)		
7)		
8)		
9)		
10)		
11)		
12)		
13)		
14)		
15)		

7. Reference

- WHO Operational Guidelines for Ethical Review Committee That Review Biomedical Research (Geneva 2000 www.who.int/tdr/publications/publications/ - accessed 11 February 2005)
- ICMR –FERCAP-WHO Training Course on Standard Operating Procedures (SOPs) For Ethics Committee Members 30th AUGUST To 1st SEPTEMBER, 2006 *Held at* National Institute for Research in Reproductive Health, Mumbai Division / www whoindia.org/Link Files/Clinical Trials Training Course_ on_Standard_Operating_Procedure_(SOPs)_for_Ethics_Committee_Members. pdf
- National Ethical Guidelines for Health Research 2011 PNHRS
- ICH E6: GCP 1996.