Table of Contents

1. Purpose

The purpose of this SOP is to provide instructions on the review and follow-up, if appropriate, of Final Reports for any study previously approved by the CHH IRB.

2. Scope

This SOP applies to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the CHH IRB.

Although CHH IRB provides an End of Study Report Form (HRP-IRB-020, see Annex 1) to the investigator, any mechanism (letter format, form provided by the Sponsor, etc.) may be used, provided that the information submitted is sufficient.

3. Responsibility

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

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Activities before a Board meeting	CHH IRB Secretariat
II	Activities during the Board meeting	CHH IRB Secretariat / Members / Chairperson
III	Activities after the Board meeting	CHH IRB Secretariat

5. Detailed instructions

5.1 Activities before a Board meeting

- See SOP/008/05 (Management of Protocol Submission) for receiving and checking the report packages.
- The Secretariat reviews the submitted report and briefs to the Chairperson.
- Make a sufficient number of copies.

5.2 Activities during the Board meeting

- Each Board member reviews a copy of the Final Report.
- The Chairman or designee entertains any discussion of the study.
- If appropriate to the discussions, a CHH IRB member may call for consensus on whether to request further information or to take other action with the investigator.
- Summarize what action should be taken.

5.3 Activities after the Board meeting

- Notify the investigator of the decision.
- Accept and file the Final Report, if no action is taken.
- Note the decision in the meeting minutes
- Consider the study as closed.

- Get a copy of the final report signed by the Chairperson or the designee.
- Send an acknowledged letter to the investigator.
- Archive the entire study protocol and the report.

6. ANNEX 1:

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

END OF STUDY REPORT FORM
Form HRP-IRB-020

Date Filed :		
Protocol No.:	Assigned No.: ☐☐☐/☐☐☐☐-☐☐	
Protocol Title :		
Principal Investigator:	E-mail address:	Phone number:
Sponsor's Name & Address:	E-mail address:	Phone number:
Study site(s):	Total Number of study participants:	No. of Study Arms:
Number of participants who received the test articles:	Study materials:	Study dose(s):
Treatment form:		Duration of the study:
Objectives:		

SUMMARY OF STUDY:

Total Number of Subjects Enrolled :	Total Number of Withdrawals :
Total Number of SAE's : _____	Reason for Withdrawals:
a) Deaths	a) Lost to Follow-up
b) SAE other than Death (please indicate SAE's)	b) Personal reasons
	c) Others (please specify)

_____ Signature of PI

_____ Date

STUDY REPORT FORM

Page 1 of 1

7. References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- National Ethical Guidelines for Health Research 2011 PNHRS