



**CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**



Version 1

SOP 10 Writing and Revising SOP

Effective Date:
January 02,
2019


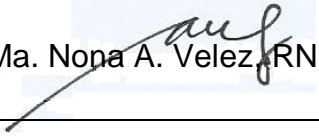
Supersedes:	Previous SOPs
Prepared by:	SOP Team 2019
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Reviewed Date:	December 14, 2018
Approved by:	 Ma. Nona A. Velez, RN, MN
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1. Policy Statement

The SOPs will provide clear, unambiguous instructions so that the related activities in the institutional review board.

2. Objective

This SOP shall define the process for writing and revising SOPs used by the CIM-CVGH Institutional Review Board (IRB).

3. Scope

This SOP provides instructions on how the CIM-CVGH IRB Standard Operating procedures are prepared, approved and distributed. It begins with the organization of an SOP team, and end with the filing and distribution of the approved SOP.

4. Responsibility

It is the responsibility of the Chair and the Board members as well as the secretariat to complete a written communication record for telephone or interpersonal discussions related to the past, present and/or future studies and/or processes involving the IRB.

5. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
<i>Step 1: Organize an SOP Team</i>	<i>Chair</i>
<i>Step 2: Design the format, layout, identifier of SOP</i>	<i>SOP Team</i>
<i>Step 3: Write a new SOP and submit to Chair</i>	<i>SOP Team</i>
<i>Step 4: Review new SOP in full board meeting</i>	<i>IRB Members</i>
<i>Step 5: Approve new SOP</i>	<i>Medical Director</i>
<i>Step 6: Distribute approved SOPs and keep copies in the IRB files.</i>	<i>IRB Secretariat</i>
<i>Step 7: Review and request for a revision of an existing SOP</i>	<i>IRB Chair, Members</i>
<i>Step 8: Training on SOP</i>	<i>IRB Members</i>
<i>Step 9: Manage and archive superseded SOPs</i>	<i>IRB Staff</i>



6. Description of Procedures

Step 1: Organize an SOP Team

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

Step 2: Design the format, layout, identifier of SOP



- An SOP is written according to the following format:

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- Number and version
 - Title
 - Policy
 - Objectives
 - Scope which includes description and purpose of the SOP
 - A flowchart when necessary
 - Detailed instructions
 - Forms (if applicable)
- Assign an identifier to the SOP
 - Each SOP should be given a number and a title that is self-explanatory and is easily understood. For the CIM-CVGH IRB SOPs, the following format is used: CIM-CVGH-RER.SOP.XXX where XXX is a three-digit number corresponding to the chapter/section in the manual where the SOP is found. The YYY is a three-digit number identifying the issue number of the SOP which will also correspond to the number of revisions made, and mm/dd/yy is the dateline to identify the year when SOP was implemented.
 - Thus, the SOP on writing of SOPs is identified as CIM-CVGH-IRB. No. .001, with Issue No. 001 and Issue Date of _____: meaning that the SOP can be seen in Chapter 1 of the SOP manual, it is the first version (Issue No. 001), with no revisions made and was implemented on _____
 - The layout of a typical SOP uses a header with the following elements:
 - Institutional seal or logo
 - Name of institution
 - SOP identifier
 - SOP title
 - Issue number
 - Issue date
 - Page number

Step 3: Write a new SOP and submit to Chair

- The SOP Team makes a draft of the SOP based on the design and format detailed above. The SOP Team submits completed draft to the Chair. The SOPs should contain details under the following main topics
 - Introduction – contains a statement of ethical principles that will guide the IRB
 - Structure and Composition of the IRB – describes the composition of REC membership with specific review functions

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- Initial Review Procedures – describe types of review and initial review procedures
- Monitoring Procedures – describe how the 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

Step 4: Review new SOP in full board meeting

- The Chair submits the draft to full board review where IRB members deliberate on the draft
- Upon full board approval, the Chair submits the approved draft to the Medical Director for final approval.

Step 5: Approve new SOP

- The CIM-CVGH Medical Director approves the SOP by signing in the appropriate section in the cover page.
- The approved SOPs will be implemented from the date of approval by the Medical Director.

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



- Distribute approved SOPs and keep copies in the IRB files.
- Upon approval of CIM-CVGH Medical Director, the Secretariat distributes SOP to CIM-CVGH IRB members, and publishes the SOP through the School/Hospital website.
- The Secretariat distributes the printed copy of the approved SOPs to the CIM-CVGH IRB members and staff; with an electronic copy published through the School/Hospital website.
- The Secretariat retains one complete originally signed SOPs copy.

Step 8: Training on SOP

- 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)

Step 9: Manage and archive superseded SOPs

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

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7. History of SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
<i>01</i>	<i>November 14, 2018</i>	<i>SOP Team</i>	<i>First Draft</i>

8. References:

- Philippine Health Research Ethics Board (PHREB) Workbook 2015
- 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
- <http://chonghua.com.ph/irb/SOP.html>