



**Eastern Visayas Health Research and Development Consortium-
Ethics Review Committee (EVHRDC-ERC)
STANDARD OPERATING PROCEDURE**

CHAPTER 5: WRITING AND REVISING SOPs

WRITING AND REVISING ERC SOP	SOP No.	33
	Version No.	04
	Version Date	04-25-2023
	Effective Date	04-30-2023

1. STATEMENT OF POLICY

The SOP provides instruction on how the Ethics Review Committee Standard Operating Procedures are prepared, approved and distributed. The SOP ensures efficiency, transparency, and consistency of ERC operations. The SOP manual needs to be periodically reviewed to determine the need for revision or new SOPs in order to respond to emerging operational issues of the ERC. The SOP Manual will be reviewed every three (3) years to assess if there are new ERC procedures that require an additional SOP and revise as needed.

2. OBJECTIVE/S OF THE ACTIVITY

Writing and revising SOPs ensures continuing quality assurance of ERC functions.

3. SCOPE AND APPLICABILITY

This SOP on Writing and Revising the ERC SOP covers the procedures the ERC has put in place in order to be able to develop new and relevant SOPs and to revise and update old SOPs. This SOP applies to all ERC activities involved in the development of its SOPs and their revisions as published and distributed by the EVHRDC. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

4. ROLES AND RESPONSIBILITIES

It is the responsibility of the ERC Chair to organize a meeting in order formulate the SOPs of the ERC.

ERC Chair - convenes an ERC meeting to review and finalize draft SOPs and submit the final draft to the EVHRDC Chair for final approval.

ERC Member Secretary and **ERC Staff Secretary** - responsible for keeping all versions of SOPs and ensuring that all ERC members have access to current versions of SOPs to guide them in the performance of their functions.

EVHRDC Chair – reviews and approves the EVHRDC ERC SOPs.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Proposal for the writing/ revising of SOP	ERC Members
Step 2: Designation of the SOP team	ERC Chair
Step 3: Drafting of the SOP revision or new SOP	SOP Team
Step 4: Review and approval of SOP	ERC Members
Step 5: Submission of the SOP to the EVHRDC Chair	ERC Staff Secretary, EVHRDC Chair
Step 6: Inclusion of the new or revised SOP in the SOP Manual and its dissemination	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Proposal for the writing/ revising of SOP

Any EVHRDC member may propose the revision of the SOP using **Form 33.1 Request for Revision of an SOP or Guideline**. The ERC Chair determines the need for writing/revising SOP and advises the proponent to present it during regular/special meetings for deliberation.

6.2 Designation of the SOP team

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

6.3 Drafting of the SOP revision or new SOP

The design the format and layout of an SOP is based on the following guidelines and **Form 33.2 SOP Template**:

- 6.3.1 **Title**, which is descriptive of contents
- 6.3.2 **Number and Version**, which follows the SOP on coding of SOPs and Guidelines

- 6.3.3 **Statement of Policy**, which dictates the way the committee intends to conduct the SOP
- 6.3.4 **Objective/s of the Activity**, which defines the purpose and intended outcome
- 6.3.5 **Scope and Applicability**, which defines the extent of coverage of the SOP and its limitations
- 6.3.6 **Roles and Responsibilities**, which delineates tasking and accountabilities for SOP implementation
- 6.3.7 **Workflow**, which is a diagram or a matrix briefly showing the different steps involved in the activity and the responsible persons.
- 6.3.8 **Description of Procedures**, which elaborates the steps outline in workflow
- 6.3.9 **Forms and Tools**, which are documents to be filled out or accomplished by different parties as required by the SOP, with a list of forms
- 6.3.10 **History**, which is a tabulation of the version dates and number, authors, and the enumeration of major changes that the SOP has undergone
- 6.3.11 **References**, which lists the instruments used to draft the Guidelines such as other SOPs, guidelines or policies
- 6.3.12 **Glossary**, which is a list of terms, including acronyms and abbreviations used in the SOP that need to be defined or explained

Each SOP should be given a number and a title that is self-explanatory and is easily understood. For the ERC SOPs, the following format is used: ERC SOP XX where XX is the number corresponding to a specific SOP. The header of each page of the SOP Manual will contain the chapter number, SOP number and title of the SOP, the version number and dates of approval and effectivity of the version.

6.4 Review and approval of SOP

The ERC members deliberate the drafted SOP in terms of relevance to the current trends in health research.

As the ERC sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier of an SOP is considered substantial).

- Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures.
- Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary. When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the ERC. A draft of the revised SOP will be discussed by the ERC members. The draft version will be reviewed by the ERC Chair who will submit it to the EVHRDC Chair for approval. Any member of the committee may propose the revision of the SOPs. Any proposal for revision must be written and submitted to the committee for review, approval, coding, and inclusion into the document.

The proposal is discussed and acted upon through full board review. The SOP team drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form. The ERC Chair submits the draft to full board review where ERC members deliberate on the draft.

6.5 Submission of the SOP to the EVHRDC Chair

The ERC Staff Secretary prepares the final form of the SOP incorporating the necessary recommendations, corrections, agreement and indicating the SOP No., Version No., Version Date and Effective Date; with the signature of the ERC Chair and submits it to the EVHRDC Chair for final approval.

6.6 Inclusion of the new or revised SOP in the SOP Manual and its dissemination

The ERC Staff Secretary distributes hard copies of the SOP within thirty (30) days of approval by the EVHRDC Chair. E-copies will be distributed immediately upon approval. This will be distributed and forwarded to the EVHRDC ERC members, EVHRDC Member Institutions and published in the EVHRDC website. The ERC Staff Secretary retains one complete originally signed SOPs copy and archives the superseded version of the SOP in the historical file maintained by the ERC. Superseded SOPs are clearly marked “superseded” with year of archiving stamped in the cover page.

7. FORMS AND TOOLS

Form 33.1 Request for Revision of an SOP or Guideline

Form 33.2 SOP Template

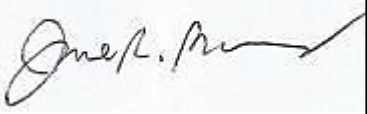

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	10/23/2015	ERC	First Draft
2	12/05/2019	ERC	Updates on procedures
3	11/25/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday	Updates on procedures and policy.

		Mr. Ricky T. Serrano Mr. Raymond G. Campo	
4	04/25/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Revised statement of policy

9. REFERENCES

- World Medical Association Declaration of Helsinki, 2013
- ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)
- WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
- International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016
- National Ethical Guidelines for Health and Health Related research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- BatMC RERC SOP 2020

Prepared by:	Reviewed and Approved by: 	Approved by: 
ETHICS REVIEW COMMITTEE	DR. JANE R. BORRINAGA, MD, FPCP ERC Chair	EXUPERIA B. SABALBERINO, MD, MPH, CESe EVHRDC Executive Committee Chair
Date: 04-25-2023	Date: 04-25-2023	Date: 04-25-2023