

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

#### **CHAPTER 1: STRUCTURE AND COMPOSITION**

### **DESIGNATION OF ERC OFFICERS**

SOP No.	02
Version No.	03
Version Date	07-10-2023
Effective Date	07-17-2023

#### 1. STATEMENT OF POLICY

The Ethics Review Committee shall have a chair, vice-chair, and member secretary who shall be selected among the members who have been with the committee for, at least one (1) year, by election in a special meeting initially presided by an outgoing officer. The ERC chair should be a medical doctor/scientist and an incumbent member of the committee for at least 2 years who is directly appointed by the EVHRDC Chair.

#### 2. OBJECTIVE/S OF THE ACTIVITY

This activity aims to ensure that the EVHRDC ERC officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

### 3. SCOPE / APPLICABILITY

The scope of this SOP includes the selection of ERC Vice-Chair and ERC Member Secretary. It starts with the call for a special meeting to select the concerned officers and ends with the filing of appointment documents of the officers. The ERC Chair is appointed by the EVHRDC Chair (see Appointment of Ethics Review Committee Members under SOP No. 01 Selection and Appointment of ERC Members).

#### 4. ROLES AND RESPONSIBILITIES

**EVHRDC Chair** – issues the Special Order and appointment of new members

**Head of EVHRDC Member Institutions** – appoint representative to be a member of the ERC

**ERC Chair** – presides the election of officers

**ERC Staff** – collects and files pertinent documents

#### 5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Appointment of new ERC Chair	EVHRDC Chair	1 day
Step 2: Nomination and election of Vice-Chair and Member Secretary	ERC Members	1 day
Step 3: Signing of Terms of Reference	ERC Officers	1 day
Step 4: Filing of documents and documentation	ERC Staff Secretary	7 working days

#### 6. DESCRIPTION OF PROCEDURES

#### 6.1. Appointment of new ERC Chair

The EVHRDC Chair appoints the ERC Chair among the medical/scientific representatives of EVHRDC member institutions.

#### 6.2. Nomination and election of Vice-Chair and Member Secretary

The ERC Chair presides over the nomination process of the ERC Officers, which include the Vice-Chair and Member Secretary. Election of officers shall be by secret ballot and is based on the majority rule. A tie shall be settled by a "toss-coin" or alternative process.

### 6.3. Signing of Terms of Reference

The ERC Chair officially notifies the officers of their election through a letter informing the officers of their election. The officers are requested to sign **Form 1.3 Appointment with Terms of Reference**. The concerned officers forthwith report to the ERC office to sign the conforme documents.

#### 6.4. Filing of documents and documentation

The ERC Staff secretary files the appointment papers accordingly (see SOP No. 29 Management of Active Files (Administrative and Study Files)).

Responsibilities of the ERC Chair

- Presides over the ERC meetings and is directly reporting to the EVHRDC Executive Committee
- Prepares an annual report summarizing ERC activities and decision outcomes
- Ensures sufficient financial and administrative support for ERC operations
- Monitors available training/s related to research ethics for the continuing education of ERC members

- Represents the ERC interests within the EVHRDC Member Institutions
- Represents the ERC to the external organizations and entities
- Principally responsible for the classification of study protocols received and assignment of Primary Reviewers
- Attend training updates on research ethics
- Serve as primary reviewer
- Declare COI and sign confidentiality agreement

## Responsibilities of the ERC Vice-Chair

- Presides over meetings in the absence of the Chair
- Classifies study protocols and assign Primary Reviewers in the absence of the Chair
- Performs other duties as designated by the Chair
- Attend research training updates
- Serve as primary reviewer
- Declare COI and sign confidentiality agreement

## Responsibilities of the Member - Secretary

- Supervises the ERC Staff
- Calendars meetings, takes the minutes and releases notice of meetings to all members
- Ensures good ERC documentation
- Ensures overall ERC compliance with good clinical practice
- Classifies study protocols and assign Primary Reviewers in the absence of the Chair and Vice Chair
- Attend research ethics training updates
- Serve as primary reviewer
- Declare COI and sign confidentiality agreement

### 7. FORMS AND TOOLS

### Form 1.3 Appointment with Terms of Reference

#### 8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	11/28/2022	Dr. Jane R. Borrinaga	First draft
		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	
		Wil. Raymona G. Campo	
2	04/25/2023	Dr. Jane R. Borrinaga	Updated
		Ms. Sarah B. Delorino	Scope/Applicabili
		Engr. Florentino L. Quiñones	ty and added
		Ms. Noreen S. Buhat	timeline in the
		Fr. Charles Gingco	Workflow
		Dr. Jose Carlo K. Del Pilar	
		Ms. Erleta S. Piñero	
		Atty. Alma Sonia Q.	
		Sanchez-Danday	
		Mr. Ricky T. Serrano	
		Mr. Raymond G. Campo	
3	07/10/2023	Dr. Jane R. Borrinaga	Updated
		Ms. Sarah B. Delorino	Workflow and
		Engr. Florentino L. Quiñones	Description of
		Ms. Noreen S. Buhat	Procedures
		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	
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## 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	<b>EXUPERIA B. SABALBERINO, MD, MPH, CESe</b> EVHRDC Executive Committee Chair
Date: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023