



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

PREPARING FOR AN ERC MEETING	SOP No.	22
	Version No.	06
	Version Date	04-25-2023
	Effective Date	04-30-2023

1. STATEMENT OF POLICY

Meetings are one of the major activities of the research ethics committee. They are venues for deliberations and decision-making regarding ethical evaluation of study proposals and are opportunities for the ERC to be informed, and to be updated regarding its operations and relevant administrative matters.

The ERC shall hold two meetings, every second Friday of the other month for full board meetings and last Tuesday of the month for Expedited Primary Reviewer (PR) meetings. Special meetings shall be held to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity.

2. OBJECTIVE/S OF THE ACTIVITY

Preparation of a meeting aims to ensure systematic, organized, independent, efficient, and comprehensive conduct of the meeting.

3. SCOPE / APPLICABILITY

This activity prepares the officers, members, and the ERC Staff Secretary who are all involved during the conduct of the Committee’s Review and Meeting.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the ERC Chair, members, ERC Staff Secretary and others, who may be involved during the conduct of Board Review and Meeting.

ERC Chair - sets the agenda, determines the need for resource person(s)/ expert(s) and other invitees based on the agenda and instructs the ERC Staff Secretary to prepare the invitation letter/s accordingly.

ERC Member Secretary - supervises the ERC Staff Secretary in confirming attendance to the meeting and preparing for the meeting.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Setting of Agenda for the Meeting	ERC Chair
Step 2: Determination of invitees	ERC Chair
Step 3: Sending of the Notice of Meeting with the agenda	ERC Staff Secretary
Step 4: Confirmation of attendance to the meeting	ERC Staff Secretary
Step 5: Preparation of logistics for the meeting	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Setting of Agenda for the Meeting.

The ERC Chair sets the draft agenda one week before the meeting. The agenda is determined from the documents received by the staff secretary, as follows; new protocols, Revised protocols, Protocol with Amendment, Continuing Review Application (Renewal of Ethical Clearance), Final Reports, Protocol Deviations, Protocol Noncompliance, Early Study Termination, Site visit evaluation report and other administrative matters. The staff secretary uses **Form 23.1 Provisional Agenda of the Full Board Review Meeting or Form 23.2 Provisional Agenda of the Expedited Review Meeting** to classify the items and forwarded to the ERC Chair for signature. **Form 23.3 Notice of Meeting** is also prepared. During the meeting, the ERC members can add other concerns to be discussed in the other matters. The staff secretary sends a copy to the members within 7 working days before the schedule of the meeting.

6.2 Determination of invitees

The ERC Chair determines the need for consultants/expert(s) and other invitees based on the agenda and instructs the staff secretary to prepare the invitation letter accordingly.

6.3 Sending of the Notice of Meeting with the agenda

Form 23.1 Provisional Agenda of the Full Board Review Meeting or Form 23.2 Provisional Agenda of the Expedited Review Meeting, Form 23.3 Notice of Meeting and other relevant documents (minutes of the previous meeting, protocol package and evaluation forms) are sent to the members for their reference and guidance.

6.4 Confirmation of attendance to the meeting

The staff secretary shall follow up confirmation of attendees a week before the meeting. The staff secretary shall ensure that members who will attend shall constitute a quorum. If some members cannot attend, alternate members are invited to ensure quorum.

6.5 Preparation of logistics for the meeting

The staff secretary prepares the venue and equipment 1 day before the meeting. The meals are requested 10 working days before the meeting. This will be served during the meeting.

7. FORMS AND TOOLS

- Form 23.1 Provisional Agenda of the Full Board Review Meeting
- Form 23.2 Provisional Agenda of the Expedited Review Meeting
- Form 23.3 Notice of Meeting

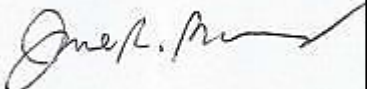

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	12/05/2012	Dr. Jane R. Borrinaga	First draft
2	10/23/2015	Dr. Jane R. Borrinaga	Updates on procedures
3	05/27/2016	ERC	Updates on procedures
4	12/05/2019	ERC	Adopt recommendation from PHREB CSA
5	11/28/2022	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	
6	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 description of procedures

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