



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

CONDUCT OF FULL BOARD MEETINGS	SOP No.	24
	Version No.	04
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

ERC Full Board Meetings are systematic, organized, confidential, collegial, competent, efficient, interactive, impartial, independent, and comprehensive. The full board meeting on protocol review and administrative meetings are conducted on the second Friday of the next month. For expedited meetings, see **SOP No. 07 Expedited Review**. Special meetings will follow **SOP No. 25 Conduct of Special Meetings**.

The meetings may be conducted on the following platform as decided by the Chair:

- a. For onsite meetings, physically present
- b. For online meetings, members attending virtually
- c. Hybrid meetings, face-to-face and virtual attendance

Attendance and quorum will be documented for Face-to-Face attendees by signing a physical attendance sheet. As for online attendees, screenshots will be taken during the meeting and before adjournment. The Zoom recordings will also show all ERC members who joined virtually.

2. OBJECTIVE/S OF THE ACTIVITY

It aims to ensure systematic, organized, independent, efficient, and comprehensive conduct of full board meetings.

3. SCOPE / APPLICABILITY

This activity guides the officers and members, and other persons who may be involved in the conduct of the meeting.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the officers and members, and other persons who may be involved in the conduct of 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: Call to order	ERC Chair
Step 2: Declaration of quorum	ERC Member Secretary
Step 3: Approval of the provisional agenda	ERC Members
Step 4: Disclosure of conflict of interest	ERC Chair
Step 5: Review and approval of the minutes of the previous meeting	ERC Chair, ERC Members
Step 6: Business arising from the minutes of the previous meeting	ERC Chair
Step 7: New business	ERC Chair, ERC Members
Step 8: ERC operations-related matters	ERC Chair, ERC Members
Step 9: Other matters	ERC Chair, ERC Members
Step 10: Meeting adjourned	ERC Chair
Step 11: Filing of documents and documentation	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Call to order

The ERC Chair calls the meeting to order.

6.2 Declaration of quorum

The ERC member secretary determines if the attendance is a quorum. A quorum is declared if attendees in the meeting are composed of half of the total number of members plus one (1), inclusive of the presence of one (1) non-affiliated and one (1) non-scientist during the meeting.

6.3 Approval of the provisional agenda

The chair invites the members to examine the provisional agenda and to propose addition or deletion of items. A motion for its approval with or without revision is to be seconded by the ERC members.

6.4 Disclosure of conflict of interest

The ERC Chair asks the members for any conflict of interest/ involvement in any of the protocol and must sign the **Form 24.1 Conflict of Interest Declaration (Protocol Review)** and **Form 24.2 Confidentiality Agreement**. A member with a COI will leave the room and will not participate in the discussion. If so, then the quorum has to be reconsidered.

6.5 Review and approval of the minutes of the previous meeting

Minutes of previous meetings which have been sent to the members prior to the meeting will be commented upon by the members by page. Comments will be recorded and integrated into the corrected minutes. A motion for its approval with or without revision is to be seconded by the ERC members.

6.6 Business arising from the minutes of the previous meeting

The presiding officer reports on administrative concerns taken up in the previous meeting.

6.7 New business

The meeting will proceed based on the approved agenda. The ERC chair presides over the discussion of the agenda. The ERC chair summarizes the issues raised, identifies the items resolved and unresolved. The ERC chair then invites the members to determine whether they are ready to decide. If not, then subsequent actions should be determined. Decisions are reached through a majority vote. In case of a tie, the members will have another discussion and voting until the body arrives at a majority decision. If there is still a tie, the chair will make the final decision.

For protocols that require clarifications from the investigator/researcher, they are invited for a clarificatory interview. The investigator/researcher were invited using

Form 27.6 Letter for Clarificatory Interview indicating the date, requested time, and venue. Alternatively, the ERC could arrange a teleconference meeting if they will not be able to appear in person.

If the ERC members do not have the necessary expertise to review certain protocols, an independent consultant is invited (*see SOP No. 03 Appointment of Independent Consultants*).

6.8 ERC operations-related matters

ERC operations-related matters are presented by the ERC chair. These may include the Work and Financial plan of the ERC and other matters that concern the committee.

6.9 Other matters

Other matters in the agenda are presented by the ERC chair. The chair will also ask the body for other concerns, which are not included in the agenda that may be included under such other matters.

6.10 Meeting adjourned

The meeting adjournment should be moved and seconded.

6.11 Filing of documents and documentation

The ERC Staff Secretary records and keeps the minutes of the meeting.

7. FORMS AND TOOLS

- Form 24.1 Conflict of Interest Declaration (Protocol Review)
- Form 24.2 Confidentiality Agreement
- Form 26.1 Minutes of the Meeting

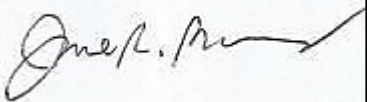

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	12/05/2019	Dr. Jane R. Borrinaga	First draft
2	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	Updates on procedures and policy.

		Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	
3	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, workflow, and description of procedures
4	07/10/2023	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 SOP Title to Conduct of Full Board Meetings and 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: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023