



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

PREPARING THE MINUTES OF MEETING	SOP No.	26
	Version No.	02
	Version Date	04-25-2023
	Effective Date	04-30-2023

1. STATEMENT OF POLICY

The Minutes of the Meeting shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

The minutes of meeting shall reflect the major discussion points and decisions during the board meeting.

2. OBJECTIVE/S OF THE ACTIVITY

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an ERC meeting.

3. SCOPE AND APPLICABILITY

This SOP includes ERC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the minutes of the meeting template and ends with the filing of the approved minutes.

4. ROLES AND RESPONSIBILITIES

Compliance shall be the responsibility of the ERC Chair, ERC Members and ERC Staff Secretary.

ERC Staff Secretary - prepares the minutes of the meeting template, records the proceedings, and facilitates approval of the Minute of the Meeting.

ERC Member Secretary, ERC Chair and ERC Members - check and ensure correctness of the minutes of the meeting.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Entry of preliminary information on the minute's template	ERC Staff Secretary
Step 2: Preparation of the draft minutes	ERC Secretary, Member Secretary, ERC Staff Secretary
Step 3: Notation of the draft minutes	ERC Secretary, Member Secretary, ERC Staff Secretary, ERC Chair
Step 4: Approval of the minutes in the next ERC meeting	ERC Chair, ERC Members
Step 5: Storage of the approved minutes	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Entry of preliminary information on the minute's template

The ERC staff secretary, under the supervision of the ERC member secretary or ERC chair, organizes the documents in the minute's template ahead of the meeting using **Form 26.1 Minutes of the Meeting**.

6.2 Preparation of the draft minutes

On site meetings– The Staff Secretary is tasked with the documentation of the proceedings in accordance with the agenda. The Member Secretary may do real time note-taking while the template of the agenda is projected on screen. The information that is included are the following: comments and recommendations on the scientific issues, ethical issues and informed consent form issues. It is understood that the opinions and actions included in the minutes are understood to be collective and should not be attributed to a specific member. The ERC Chair ensures that the fulfillment of this task by the ERC staff secretary.

Online meetings – The Member Secretary does the real time note taking on the agenda template projected on the online platform and screen shared.

Blended (on site/online) meetings - The Member Secretary does the real time note taking on the agenda template projected on both the onsite and online platform and is screen shared.

6.3 Notation of the draft minutes

The staff secretary or member secretary prepares the draft minutes, and forwarded to the ERC chair within 48 hours for checking and notation. In the general, the following items are included in the minutes of the meeting:

- Date and venue of meeting
- Members attendance (members present and absent)
- Presence of Independent consultants, primary investigators, guests and observers
- Time when the meeting was called to order
- Declaration of Quorum
- Name of presiding Officer
- Conflict of interest (COI) declaration
- Items discussed, issues raised and resolutions
- ERC decisions and recommendations
- Name and signature of person who prepared the minutes
- Name and signature of the chair and date of notation

6.4 Approval of the minutes in the next ERC meeting

The approval of the minutes of the expedited review meeting and the full board meeting is done during the next full board meeting (every 2nd Friday of the next month) through a formal motion of any member and seconded accordingly.

6.5 Storage of the approved minutes

The ERC maintains a central file of all meeting minutes by year to facilitate retrieval and stored in a filing cabinet. Digital copies of the minutes of the meeting are also filed by year in a password protected digital folder saved both in the external hard drive and Google drive. In addition, a copy of the excerpts of the minutes when the protocol was reviewed and when it was finally approved are filed in the appropriate protocol file folder.

7. FORMS AND TOOLS

Form 26.1 Minutes of the Meeting

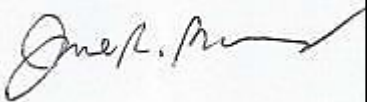

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	11/28/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat	First draft

		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	
2	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 and 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