



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

**CHAPTER 4: DOCUMENTATION AND ARCHIVING**

<b>CONDUCT OF SPECIAL MEETINGS</b>	SOP No.	25
	Version No.	01
	Version Date	11-11-2022
	Effective Date	01-01-2023

**1. STATEMENT OF POLICY**

Special meetings shall be held either onsite or online to resolve issues that require immediate attention, e.g. oversight problems involving the safety of participants, protocol violation that impact research integrity, RNE clarificatory meetings, clarificatory interviews/dialogue with PI and urgent administrative and operational concerns of the ERC.

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

Special meetings are conducted to provide an opportunity for the ERC to arrive at collegial decisions on issues requiring immediate attention about on-going study protocols and urgent administrative and operational concerns of the ERC.

**3. SCOPE AND APPLICABILITY**

This SOP describes the process in conducting special meetings. The SOP begins with the preparation for the special meeting and ends with the collection, storage and disposal of meeting materials.

**4. ROLES AND RESPONSIBILITIES**

Compliance shall be the responsibility of the ERC Chair and ERC members, and other persons who may be involved in the conduct of regular meetings and special meetings.

**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: Preparation for the conduct of special meeting	ERC Chair, ERC Member Secretary, ERC Staff Secretary
Step 2: Determine quorum	ERC Staff Secretary
Step 3: Declaration of conflict of interest	ERC Chair
Step 4: Reading and approval of the agenda	ERC Chair, ERC Members
Step 5: Discussion of the agenda	ERC Members
Step 6: Meeting adjourned	ERC Members
Step 7: Collection and storage or disposal of meeting materials	ERC Staff Secretary

## 6. DESCRIPTION OF PROCEDURES

### 6.1 Preparation for the conduct of special meeting

A special meeting may be called by the ERC Chair or is proposed by a member of the ERC. The decision to call a special meeting is based on the following criteria:

Oversight problems requiring immediate action if delay will affect or have impact on the safety of participants

- Protocol violations that impact on research integrity
- Occurrence of onsite SAEs and SUSARs
- Urgent ERC activities such as but not limited to selection of new member or officer, approval of new or revised SOP, budget deliberation, accreditation applications, trainings and other unexpected administrative or operational events that would affect the ERC
- Clarificatory meetings / interview / dialogue

The ERC Chair or ERC Member Secretary or ERC Staff Secretary inform all members, including invited guests, if any, about the special meeting, date, time and venue, or if online, the platform link to be used, through various channels such as call, messaging, or through electronic mail. Confirmation of attendance will be noted to ensure availability of quorum during the special meeting. Notice of meeting and agenda will be sent through electronic mail.

## **6.2 Determine quorum**

The ERC staff secretary determines if the attendance is a quorum. A quorum is 50% of the total number of the members plus 1 with the inclusion of the non-institutional and non-scientist members.

## **6.3 Declaration of conflict of interest**

After the quorum has been determined, the ERC Chair calls the meeting to order. The ERC Chair asks the members for any conflict of interest (COI) involving the items listed in the agenda. A member with a COI will leave the room and will not participate in the discussion.

## **6.4 Reading and approval of the agenda**

The ERC Chair presents the agenda to the members. A motion for the approval of the agenda must be seconded for final adoption.

## **6.5 Discussion of the agenda**

The ERC Chair presides over the discussion of the agenda. The ERC Chair summarizes the issues raised, identifies the items resolved and unresolved. For clarificatory interview/meeting, attendees may be composed of the ERC Chair or ERC Vice-Chair, Primary Reviewers, the Principal Investigator and if necessary, an independent consultant.

A special meeting may be conducted between the members through electronic communication, i.e. tele or video conference. Independent Consultants may be invited for a special meeting or during clarificatory interview for purposes of clarifying study protocol related to their fields of expertise. As in the case of regular meetings, they will not be counted for quorum and are not allowed to vote for Full Board actions.

The meeting is conducted in the same sequence as Full Board Review with similar corresponding actions. Minutes of the special meeting shall follow the same sequence as regular meetings. Resolutions on the minutes of the special meeting will be reported accordingly during the full board meeting.

## **6.6 Meeting adjourned**

The meeting adjournment shall be moved and seconded. The ERC staff secretary shall record the issues and concerns raised during the meeting. The staff secretary shall record and keep the minutes of the meeting.

## **6.7 Collection and storage or disposal of meeting materials**

In case of face-to-face meetings, the ERC Staff Secretary collects all meeting materials, including documentation collected for the Minutes of the meeting.

All meeting materials that must be stored are filed in the relevant study files in a manner prescribed in **SOP No. 29 Management of Active Files (Administrative and Study Files)** and **SOP No. 30 Archiving Files**.

In case of online meetings, the ERC staff secretary shall save and store the digital files in cloud accordingly in the different folders in password protected Google drive accessible only to the ERC Chair and ERC Member Secretary.

## 7. FORMS AND TOOLS

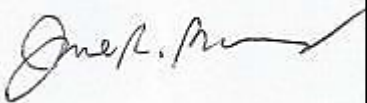

Form 26.1 Minutes of the Meeting

## 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 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	First draft

## 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: 
<b>ETHICS REVIEW COMMITTEE</b>	<b>DR. JANE R. BORRINAGA, MD, FPCP</b> ERC Chair	<b>EXUPERIA B. SABALBERINO, MD, MPH, CESe</b> EVHRDC Executive Committee Chair
Date: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022