



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

CHAPTER 3: POST APPROVAL PROCEDURES

REVIEW OF RNE REPORTS	SOP No.	16B
	Version No.	01
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

The ERC shall require the submission of RNE reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved. Reportable Negative Event (RNE) is an adverse event or incident that has the potential to be classified by the ERC as an unanticipated problem posing risks to participants or others. An incident is determined to be reportable to the ERC when it is both: probably or definitely related to participation in the research. It occurs during the implementation of a research that impacts safety, dignity and well-being of participants and /or the study team and the integrity of data. These events need to be reported by PI to the ERC as essential to the continuing concern for a favorable balance of risks and benefits from the study

2. OBJECTIVE/S OF THE ACTIVITY

The review of RNE reports aims to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated.

3. SCOPE / APPLICABILITY

This SOP applies to the review of RNE reports. The SOP begins with the receipt and documentation of submission of RNE report in the logbook/database and ends with the filing of all related documents and update of the protocol database.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the principal investigator, ERC Staff Secretary and the ERC Members.

Principal Investigator - report the Reportable Negative Events.

ERC Staff Secretary - receives and logs the Reportable Negative Events and forwards to the ERC Chair.

ERC Chair - calls out for a special meeting for a clarificatory meeting with the ERC members and the research team.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: The Principal Investigator submits the RNE Report	Principal Investigator
Step 2: Retrieval of pertinent protocol file	ERC Staff Secretary
Step 3: Notification of ERC Chair	ERC Staff Secretary
Step 4: Call for a special meeting	ERC Chair
Step 5: Conduct of special meeting	ERC Members
Step 6: Communicate ERC decision	ERC Staff Secretary
Step 7: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 The Principal Investigator submits the RNE Report

The PI submits **Form 16B.1 Reportable Negative Events**. The staff secretary receives the accomplished RNE report form and enters the submission into the logbook. The staff secretary notes whether the submission is within the required timeline.

6.2 Retrieval of pertinent protocol file

The staff secretary retrieves the approved protocol file and checks the identity of the primary reviewers.

6.3 Notification of ERC Chair

The staff secretary notifies and sends the report and the retrieved documents to the ERC Chair who may decide to call for a special meeting.

6.4 Call for a special meeting

The staff secretary prepares for a special full board meeting (*See SOP No. 25 Conduct of Special Meetings*). The principal investigator and other members of the study team may be invited for a clarificatory meeting through **Form 27.6 Letter for Clarificatory Interview**.

6.5 Conduct of special meeting

The ERC Chair leads the discussion of the special meeting, summarizes the RNE report and informs the ERC members regarding the presence of the research team for clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research.

The research team is excused and the ERC members deliberate on possible options, as follows:

- recommend suspension of the study until risk is resolved
- withdrawal of ethical clearance
- submission of a plan to mitigate risk/harm
- require an amendment to the protocol
- uphold original ethical clearance

6.6 Communicate ERC Decision

After the committee makes a decision on the RNE Report of the protocol and officially signed by the ERC Chair, the staff secretary informs the PI of this decision within seven (7) working days (*see SOP No. 27 Communicating the ERC Decision*).

6.7 Filing of protocol-related documents and updating of the Protocol Database

The ERC Staff Secretary keeps copies of the document for documentation and updates the database accordingly.

7. FORMS AND TOOLS

- Form 16B.1 Reportable Negative Events
Form 27.6 Letter for Clarificatory Interview

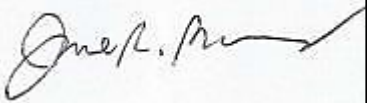

8. HISTORY

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	First Draft

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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	EXUPERIA B. SABALBERINO, MD, MPH, CESe EVHRDC Executive Committee Chair
Date: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022