



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

MANAGEMENT OF QUERIES AND COMPLAINTS	SOP No.	32
	Version No.	02
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the ERC staff secretary or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the ERC Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion. The Primary Reviewers present all protocol-related resolved queries during the next Full Board Review Meeting.

2. OBJECTIVE/S OF THE ACTIVITY

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the ERC and to ensure that the rights and well-being of participants are attended to. Communication of queries and complaints, especially from research participants, provide mechanisms that contribute both to maintaining transparency of ERC decision-making processes, as well as empowerment of study participants

3. SCOPE AND APPLICABILITY

This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the ERC. The ERC will also accept communications of queries, notifications and complaints from other parties provided these communications are relevant to ERC oversight. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the ERC meeting.

4. ROLES AND RESPONSIBILITIES

ERC Staff Secretary - is responsible for receiving participant queries and requests related to their participation, refers to relevant issues and keeps records of all actions taken by the ERC.

Member Secretary - supervises the Staff and ensures accuracy of the processes.

ERC Chair - calls for a special meeting and takes appropriate actions.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Receipt, logging, and acknowledgement of queries and complaints	ERC Staff Secretary
Step 2: Referral of query or complaint to competent authority	ERC Staff Secretary, ERC Chair, Primary Reviewers
Step 3: Formulation of response	Primary Reviewers
Step 4: Communicate ERC response	ERC Staff Secretary
Step 5: Logging of the response and inclusion in the agenda of the ERC meeting	ERC Staff Secretary
Step 6: Filing of copies of Query/Complaint Form and other documents	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Receipt, logging, and acknowledgement of queries and complaints

The ERC will maintain a logbook dedicated to queries and complaints which will include date, time, name of concerned party, specific study protocol number and title and name of principal investigator, nature of query or complaint. Complainant shall accomplish **Form 32.1 Query and Complaint Record** to be properly coded by the ERC staff secretary.

6.2 Referral of query or complaint to competent authority

The staff secretary refers queries related to specific protocols approved by the ERC to the primary reviewers. On the other hand, the staff refer all complaints to the ERC Chair who determines the level of risk affected by the issue. Minimal risk complaints are referred to the primary reviewers of the concerned protocol. Complaints that

involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The staff notifies the concerned primary reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.

6.3 Formulation of response

For queries, the primary reviewers shall accomplish the portion on “Action Taken” on the **Form 32.1 Query and Complaint Record**.

For minimal risk complaints, the primary reviewers accomplish Form 33.1 Query/Complaints Form.

For more than minimal risk, the committee may choose any of the following options:

- Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.
- Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.
- Formulate recommendation if satisfied with the adequacy of information:
 - request for explanation/justification from researcher
 - accept request/demand of participant
 - suspension of further recruitment, amendment of protocol and re-consent of participants, others

6.4 Communicate ERC response

The ERC staff secretary prepares the official communication of response to queries and complaints using **Form 27.3 Notification of ERC Decision** to be duly signed by the ERC Chair (See **SOP No. 27 Communicating the ERC Decision** for protocol-related queries).

6.5 Logging of the response and inclusion in the agenda of the ERC meeting

See **SOP No. 28 Management of Incoming and Outgoing Communications** and **SOP No. 23 Preparing the Meeting Agenda**.

6.6 Filing of copies of Query/Complaint Form and other documents

The ERC Staff Secretary stores the signed forms in the study protocol folder.

7. FORMS AND TOOLS

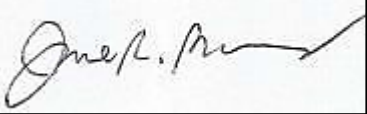

Form 32.1	Query and Complaint Record
Form 27.3	Notification of ERC Decision

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	11/21/2019	ERC	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 Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Updates on procedures and 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: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022