



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

CHAPTER 3: POST APPROVAL PROCEDURES

MANAGEMENT OF APPEALS	SOP No.	19
	Version No.	02
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

The ERC shall consider the perspective of the researcher regarding the feasibility and acceptability of ERC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved on the next scheduled full board review.

2. OBJECTIVE/S OF THE ACTIVITY

- To define the process for the appeal of the decision of the ERC in connection to the submitted protocol of the investigator which has been disapproved, suspended, terminated or modified.
- To provide a basis for continuous quality improvement of the research that has been disapproved due to the scientific values and ethical issues that has been raised by the ERC.
- To provide the investigator the opportunity to clarify, defend and provide substantial documents that would revert the decision of the ERC.

3. SCOPE AND APPLICABILITY

This SOP is applicable to all research proposals submitted to the ERC that have been reviewed and disapproved, either in a full board review or expedited review.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the ERC, the Principal Investigator and the ERC Staff Secretary.

ERC – Reviews the scientific value and ethical acceptability of the research involving human participants and provides the venue for the appeal of the ERC decision.

Investigator – Provide a written appeal for reconsideration to the ERC within 30 days from the receipt of the notice of disapproval from the ERC and the substantial

information/documents that would clarify and defend the implementation of the proposal.

ERC Staff Secretary – Ensure the proper documentation of the review and provide the necessary Decision Letter and Decision Form of the proposal to the Principal Investigator within the prescribed period.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Submission of appeal	Principal Investigator
Step 2: Receipt of the appeal and retrieval of pertinent protocol file	ERC Staff Secretary
Step 3: Notification of ERC Chair and Primary reviewers	ERC Staff Secretary
Step 4: Inclusion in the Agenda of the next regular meeting	ERC Chair, ERC Staff Secretary
Step 5: Discussion and deliberation of the appeal	ERC Chair, Primary Reviewers
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 Submission of appeal

If a Principal Investigator (PI) disagrees with an ERC decision in whole or in part, he/she may submit a written appeal to the ERC. The written appeal must use **Form 19.1 Letter of Appeal** to be submitted within 30 days of the receipt of the written notice of the disapproval. The PI should include information that supports his or her justification for bringing the appeal and addresses the specific concerns of the ERC and basis for the ERC's decision.

6.2 Receipt of the appeal and retrieval of pertinent protocol file

The ERC Staff Secretary receives the letter of appeal and enters the pertinent information into the logbook. He/She retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

6.3 Notification of ERC Chair and Primary reviewers

The ERC staff secretary notifies the ERC Chair and the primary reviewers about the letter of appeal and awaits further instructions. A copy of the protocol is distributed to the ERC Chair and primary reviewer who did the initial review.

6.4 Inclusion in the Agenda of the next regular meeting

The ERC Chair instructs the staff secretary to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

6.5 Discussion and deliberation of the appeal

The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The ERC Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides by votation whether to accept any or all of the points raised in the appeal.

6.6 Communicate ERC decision

Based on the deliberations, the ERC Chair summarizes the decision points and instructs the ERC staff secretary to prepare the draft decision letter (**Form 27.2 Letter of Modification and Form 27.3 Notification of ERC Decision**). The ERC chair approves and signs the documents and the staff secretary forwards it to the PI (*See SOP No. 27 Communicating the ERC Decision*).

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

The staff secretary files all the documents into the appropriate folder and updates the protocol database accordingly.

7. FORMS AND TOOLS

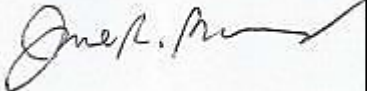

Form 19.1	Letter of Appeal
Form 27.2	Letter of Modification
Form 27.3	Notification of ERC Decision

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