



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

CHAPTER 3: POST APPROVAL PROCEDURES

STUDY PROTOCOL AMENDMENT	SOP No.	13
	Version No.	05
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

All research protocols reviewed and approved by the committee with an amendment should seek approval prior to the implementation. The Principal Investigator (PI) reports the number of amendments, the nature, and reason of the amendment.

The ERC should properly inform the principal investigator to submit an application for amendment whenever there is any change regarding the composition of the study team, the study site, the protocol and related documents that it previously approved using the Protocol Amendment Submission Form.

2. OBJECTIVE/S OF THE ACTIVITY

To ensure the required completion of the reviewed research protocol for the safety of the participants.

3. SCOPE / APPLICABILITY

This applies to all researches reviewed and approved by EVHRDC-ERC, seeking for an approval of amendment.

4. ROLES AND RESPONSIBILITIES

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

Principal Investigator - Submits the form for Study Protocol Amendment with other protocol related documents.

ERC Staff Secretary – determines the completeness and acknowledges receipt of documents.

ERC Chair - determine the type of review and identify the primary reviewers.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: The Principal Investigator submits the study protocol amendment package	Principal Investigator	15 th day of the month
Step 2: Determine the type of review	ERC Chair	3 days
Step 3: Forward amendment package to the Primary Reviewers	ERC Staff Secretary, Primary Reviewers	7 days
Step 4: Review of amendment package	Primary Reviewers	7 days
Step 5: Discuss the amendment or report the review result to the ERC during full board meeting	Primary Reviewers	Same day of review
Step 6: Communicate ERC decision	ERC Staff Secretary	7 days
Step 7: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary	7 days

6. DESCRIPTION OF PROCEDURES

6.1 The Principal Investigator submits the study protocol amendment package

The Principal Investigator (PI) submits **Form 13.1 Study Protocol Amendment** addressed to the ERC Chair through the ERC Staff Secretary together with the amendment study protocol or protocol-related documents. The Staff Secretary checks the completeness of the protocol amendment package submitted by the PI. He/she also verifies whether the Protocol Code No. and forms used are correct and records the submission in the protocol database.

6.2 Determine the type of review

The ERC Chair reviews the documents to determine whether the amendment is major or minor.

Major protocol amendments: increase risk to study participants and require full board review. These include but are not limited to the following:

- Modification of treatment – addition or reduction of treatments
- Any changes in inclusion/exclusion criteria
- Change in study design
- Additional treatment/s or the deletion of treatment/s
- Change in method of dosage formulation, such as, oral to intravenous
- Significant change in the number of subjects
- Significant decrease or increase in dosage amount
- Any other changes that will entail more than minimal risk.

Minor protocol amendments: those which are unlikely to compromise the integrity of the research or the welfare and rights of the participants and present no new ethical issues; and changes that are administrative in nature can be expedited.

The ERC Chair identifies the Primary Reviewers who did the initial review and verifies ERC approval of the initial protocol submission. If the Primary Reviewers are not available to do the review, The ERC Chair shall do the review provided he/she does not have a Conflict of Interest. Otherwise the ERC Chair designates qualified members to do the review.

6.3 Forward amendment package to the Primary Reviewers

The ERC Staff Secretary sends the **Form 13.1 Study Protocol Amendment** together with the amended study protocol with amended section clearly indicated and other documents that have been affected by the revision. The protocol package is sent at least seven (7) working days after the cut-off date.

6.4 Review of amendment package

The Primary Reviewers or his/her alternate review the amended documents and compares them with the previously approved documents in the protocol file folder to assess if the proposed amendment/s would alter the risk/benefit ratio and to make appropriate recommendations using **Form 13.1 Study Protocol Amendment**.

6.5 Discuss the amendment or report the review result to the ERC during full board meeting

For Major Protocol Amendment:

The Primary Reviewers or his/her alternate present the results of the review to the ERC during full board meeting.

The ERC decides whether or not there is a need for the PI to clarify, elaborate or explain further the amendment/s. The following are possible review decisions of the committee:

- Approval
- Minor Modification to the study protocol, subject to expedited review at the level of the panel chair.
- Major modification to the study protocol, subject to full panel review.
- Disapproval

For Minor Protocol Amendment:

The Primary Reviewers or his/her alternate submit the results of the review using the **Form 13.1 Study Protocol Amendment**. The review decision is reported to the ERC during the full committee meeting.

6.6 Communicate ERC Decision

If the amendment is approved, the ERC Staff Secretary prepares **Form 27.4 Letter of Approval of Amendments**. The form includes the approved new version number, date of amendment approval, and the list of approved amendments given to an approved protocol/ICF amendment. A statement is also included for the PI to submit the updated protocol with the assigned updated version number. Include footer in all pages that indicates both the DATE and VERSION NUMBER of the amended study protocol, ICF and other documents forming part of the protocol.

If further questions/verification are needed, the staff secretary prepares **Form 27.5 Letter of Document Receipt and Recommendations of Further Action** for signature of ERC Chair. The Staff Secretary sends the notification to the PI within seven (7) working days after the meeting.

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

The ERC Staff Secretary ensures that the version no. and date marked on the amended documents are correct. The ERC Staff Secretary keeps a copy of all protocol amendment related documents in the protocol file folder and updates the protocol file index.

7. FORMS AND TOOLS

Form 13.1	Study Protocol Amendment
Form 27.4	Letter of Approval of Amendments
Form 27.5	Letter of Document Receipt and Recommendations of Further Action

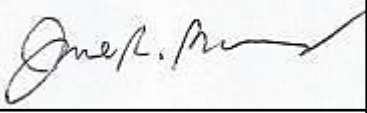

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	10/23/2015	ERC	First Draft
2	12/05/2019	ERC	
3	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.
4	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	Added timeline in the Workflow
5	07/10/2023	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	Added additional step in the timeline and description of procedures to reflect the review of the amendment package

		Mr. Raymond G. Campo	
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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: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023