



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

CHAPTER 2: INITIAL REVIEW PROCEDURES

USE OF STUDY EVALUATION FORMS	SOP No.	12
	Version No.	01
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

Assigned Primary Reviewers are required to submit duly filled-up evaluation forms to ensure an exhaustive evaluation of the study protocol’s scientific design, ethical issues, and corresponding measures to reduce the risks to human participants, as well as evaluation of informed consent processes and forms. The name of PR will be indicated on the evaluation forms by the ERC Staff Secretary after submission of PI of complete protocol package.

The protocol evaluation forms and informed consent evaluation forms shall be accomplished within 5-7 working days from receipt of the protocol package and shall be submitted one (1) day before the scheduled meeting by the Primary Reviewer.

2. OBJECTIVE/S OF THE ACTIVITY

Comprehensive review of study protocols submitted shall be ensured with the use of a guided and detailed evaluation forms to cover all aspects such as scientific design and ethical considerations in the conduct of the study and all essential elements in securing informed consent from human participants. In addition to the review elements described above, the primary reviewers shall ensure the study protocol’s compliance with existing international and national guidelines and policies including, but not limited to, the 2017 National Ethical Guidelines for Health and Health-related Research and Data Privacy Act of 2012. The evaluation forms are designed to standardize the review process and to facilitate the reporting of the findings and recommendations pertaining to the study protocol as well as related documents.

3. SCOPE AND APPLICABILITY

This SOP shall cover the use of the Protocol Evaluation Form and Informed Consent Evaluation Form in the review and evaluation of protocols and related documents

submitted to EVHRDC Ethics Review Committee for initial review and approval. This SOP begins with the review exercise and accomplishment of the evaluation forms including findings as well as recommendations and ends with the filing of the accomplished assessment forms in the respective protocol folders. There are two (2) assessment forms to be used for protocol review:

- **Form 12.1 Protocol Evaluation**
- **Form 12.2 Informed Consent Evaluation**

4. ROLES AND RESPONSIBILITIES

ERC members – shall fill up the study assessment forms after a thorough review of the submitted protocols and other related documents. Members shall provide details on the remarks section when indicated.

ERC Member Secretary - checks the completeness of the accomplished evaluation forms.

ERC Staff Secretary - collects and files the evaluation forms in the protocol file folder.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Accomplishment of study protocol and informed consent evaluation form	Principal Investigator, ERC Members
Step 2: Submission of evaluation forms to the ERC staff secretary	Principal Investigator, ERC Members
Step 3: Inclusion in meeting agenda or preparation of Approval/Decision letters	ERC Staff Secretary
Step 4: Collation of all evaluation forms and consolidation of findings	ERC Member Secretary, ERC Staff Secretary
Step 5: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

- 6.1 Accomplishment of study protocol and informed consent evaluation form**
 The assigned Primary Reviewers and, in case of Full Review, all other ERC members, accomplish completely and comprehensively **Form 12.1 Protocol Evaluation and Form 12.2 Informed Consent Evaluation** after reviewing the study protocol.

6.2 Submission of evaluation forms to the ERC staff secretary

The Primary Reviewers submit the accomplished evaluation forms one (1) day before the meeting and present during the full board review meeting. The Secondary Reviewers submit their evaluation forms during the meeting. The same procedure shall be done during the expedited review meeting. All blocks in the forms must be completely filled out, duly signed by the reviewers before submission to the ERC (wet signature if hard copy, e-signature for online submission). Submission may be through personal submission at the ERC office or through an online platform provided that the assessment forms contain the e-signature of the Primary Reviewer/ERC members.

6.3 Inclusion in meeting agenda or preparation of Approval/Decision letters

The ERC staff secretary, after collection of all filled-out evaluation forms performs the following functions:

For protocols under Expedited Review, Primary Reviewer assessment is discussed/accomplished first during Expedited PR Review Meeting prior to informing the PI. If approved, the decision is presented in the Full Board Meeting by one of the Primary Reviewers. The staff secretary prepares the **Form 27.1 Approval Letter** that is signed by the ERC Chair and sent to the Principal Investigator. If there are revisions required, these are communicated to the principal Investigator who has to resubmit the revised protocol and related documents before approval is given.

For study protocols under Full Board Review, the staff secretary includes the protocol in the agenda of the next ERC meeting for discussion and decision. The Primary Reviewer presents the protocol to the members with her/his comments. An independent consultant may be asked to elucidate on the validity and ethics of the study also using the evaluation forms. An approval letter is prepared, signed by the ERC Chair and sent to the PI once the protocol is approved. If there are revisions required, they are communicated to the Principal Investigator who has to resubmit the revised protocol and related documents before approval is given.

6.4 Collation of all evaluation forms and consolidation of findings

The ERC member secretary ensures all concerned Primary Reviewers and in case of Full Board Review, all ERC members submit and sign duly accomplished evaluation forms. The ERC staff secretary collects all the signed forms.

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

All forms duly signed by the Primary Reviewers, ERC Members and the ERC Chair are filed in the corresponding protocol folder.

7. FORMS AND TOOLS

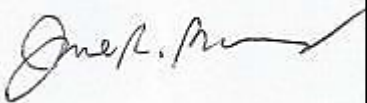

Form 12.1	Protocol Evaluation Forms
Form 12.2	Informed Consent Evaluation Forms
Form 27.1	Approval Letter

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: 
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