



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

CHAPTER 2: INITIAL REVIEW PROCEDURES

SINGLE JOINT RESEARCH ETHICS BOARD REVIEW PROCESS	SOP No.	09
	Version No.	01
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

EVHRDC ERC shall participate in a Single Joint review of a research project/proposal in which Region VIII is one of the chosen sites. The ERC will accept results of Single Joint Review except those with strong ethical issues that need to be addressed.

2. OBJECTIVE/S OF THE ACTIVITY

This activity describes the Single Joint Review procedure in the conduct of multi-site researches.

3. SCOPE AND APPLICABILITY

This SOP applies to researches to be conducted in Region VIII as part of a multi-site research joining a Single Joint Review.

4. ROLES AND RESPONSIBILITIES

SJREB Chair – presides over full board meetings and expedited reviews to ensure appropriate review of protocol related documents in accordance with international and national guidelines and regulations.

SJREB Staff Secretary – invite reviewers from ERC site, selected by the sponsors of researchers to conduct the study.

EVHRDC ERC – joins parallel reviews for proposals submitted to SJREB and EVHRDC ERC.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Receipt of protocol qualified for SJREB review	ERC Staff Secretary
Step 2: Request from SJREB for reviewers	SJREB Staff Secretary
Step 3: The ERC Chair appoints representatives/primary reviewers	ERC Chair
Step 4: Participate in the SJREB full board review	Primary Reviewers
Step 5: Communicating decision to the Principal Investigator	ERC Staff Secretary
Step 6: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Receipt of protocol qualified for SJREB review

The ERC Staff Secretary receives an invitation/protocol package from SJREB to participate in the review of a specific protocol/receives a protocol directly from the principal investigator. The ERC submits the letter of intent sent by the SJREB Staff Secretary. The letter of intent is signed by the ERC Chair. Upon acceptance of the intent to participate, the ERC Staff Secretary requests copies of the research protocol and other relevant documents.

6.2 Request from SJREB for reviewers

The SJREB may request primary reviewers (EVHRDC ERC representatives) from EVHRDC ERC for study protocols included for SJREB review.

6.3 The ERC Chair appoints representatives/primary reviewers

The ERC Chair assigns primary reviewers from the EVHRDC ERC members (usually, the chair and vice chair and non-scientific member). If not available, any scientific member and non-scientific member with no COI may be assigned. The primary reviewer does the preliminary review of the protocol, fills up the protocol evaluation form and the informed consent evaluation form. The ERC Staff Secretary forwards the scanned protocol evaluation forms and the informed consent evaluation forms.

6.4 Participate in the SJREB full board review

The EVHRDC ERC primary reviewer attends the SJREB Meeting and presents the protocol evaluation. The ERC accepts the decision of SJREB.

6.5 Communicating decision to the Principal Investigator

If the study has been approved during the SJREB meeting, copies of the minutes of the meeting and endorsements of approval are forwarded to the EVHRDC ERC by the SJREB Staff Secretary.

For protocols with strong ethical issues that still need to be addressed, the ERC has the responsibility to inform the site Principal Investigator of the outcome of the SJREB review as well as the outcome of the local ERC review.

The site ERC accepts the joint review decision and includes it in the agenda of the next full board meeting.

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

The ERC staff secretary files the research protocol reviewed in an SJREB review, together with the duplicate copies of the approval letter, decision form and accomplished SJREB evaluation forms in the protocol file folder.

The ERC staff secretary logs the documents in the protocol file index and updates the protocol database for SJREB reviewed protocols.

7. FORMS AND TOOLS

SJREB Evaluation Forms

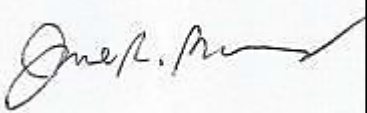

SJREB Letter of Intent

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