



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

**CHAPTER 2: INITIAL REVIEW PROCEDURES**

<b>RESEARCH INVOLVING INDIGENOUS PEOPLE</b>	SOP No.	10
	Version No.	01
	Version Date	11-28-2022
	Effective Date	01-01-2023

**1. STATEMENT OF POLICY**

The EVHRDC ERC adheres to policies and regulations regarding research involving Indigenous People. Research involving IPs must undergo ethical review for endorsement to appropriate NCIP authority. This is to ensure protection of the rights and benefits of the IPs. (PHREB Memorandum No. 2017-001 “Policies and Regulations regarding Research Involving Indigenous Peoples/Indigenous Cultural Communities)

**2. OBJECTIVE/S OF THE ACTIVITY**

This SOP aims to implement the legal procedures for the review of protocol involving Indigenous People.

**3. SCOPE AND APPLICABILITY**

This applies to research involving IPs found in Region VIII. This shall guide the ERC and other persons who may be involved in this type of research.

**4. ROLES AND RESPONSIBILITIES**

Compliance shall be the responsibility of the ERC Chair, ERC members, ERC Staff Secretary and others, who may be involved in the conduct of ERC Meetings.

**ERC Chair** - sets the agenda, determines the need for resource person(s)/ expert(s) and other invitees based on the agenda and instructs the ERC staff secretary to prepare the invitation letter/s accordingly.

**ERC Member Secretary** - supervises the ERC Staff Secretary in confirming attendance to the meeting and preparing for the meeting.

**ERC Staff Secretary** - ensures the proper documentation of the review and provides 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 research protocol	Principal Investigator
Step 2: Acknowledge receipt	ERC Staff Secretary
Step 3: Determine the type of review	ERC Chair
Step 4: Issuance of endorsement letter to NCIP	ERC Chair, ERC Staff Secretary
Step 5: Principal Investigator applies for NCIP/FPIC review and approval	Principal Investigator
Step 6: Principal Investigator submits protocol with an attached NCIP approval to the EVHRDC ERC	Principal Investigator
Step 7: EVHRDC ERC issues Approval Letter to the Principal Investigator	ERC Chair, ERC Staff Secretary
Step 8: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

## 6. DESCRIPTION OF PROCEDURES

### 6.1 Submission of research protocol

The Principal Investigator/institution must accomplish the application forms and attach three (3) copies of the research proposal together with an e-copy sent to the EVHRDC ERC email, [evhealthresearch2020@gmail.com](mailto:evhealthresearch2020@gmail.com). The documents are submitted to the EVHRDC ERC Staff Secretary during regular office hours, Mondays – Fridays, 9:00 AM to 5:00 PM (**See SOP No. 05 Management of Initial Submissions**).

### 6.2 Acknowledge receipt

The documents are stamp received, dated and signed by the ERC Staff Secretary. The protocol is assigned a code as follows:

Year-nth protocol  
(e.i. 2012-001)

Same coding may be assigned when received by the ERC member secretary/ ERC Staff Secretary after which protocol information is logged in the **Form 28.1 Submission Log and Form 28.2 Study Protocol Database**.

**6.3 Determine the type of review**

The protocol is endorsed to the ERC Chair to determine the type of review applicable to the research proposal. The types of review are as follows:

- **Full Review** – for protocols that entail more than minimal risk to participants or those that involve vulnerability issues.
- **Expedited Review** – for protocols that do not require full review such as, chart reviews, survey of non-sensitive nature, use of anonymous or anonymized laboratory/pathology samples or stored tissues or data. Requires at least 2 reviewers, one (1) scientist and one (1) non-scientist.
- **Exempt From Review** – for protocols that neither involve human participants nor identifiable human tissue, biological samples, and data.

**6.4 Issuance of endorsement letter to NCIP**

If the protocol is technically and ethically sound, the ERC issues to the PI an endorsement letter to NCIP.

**6.5 Principal Investigator applies for NCIP/FPIC review and approval**

The PI applies for NCIP approval with the endorsement letter from the EVHRDC ERC. The NCIP may have recommendations to the protocol and the PI should comply.

**6.6 Principal Investigator submits protocol with an attached NCIP approval to the EVHRDC ERC**

The PI resubmits the protocol with NCIP approval to the EVHRDC ERC.

**6.7 EVHRDC ERC issues Approval Letter to the Principal Investigator**

ERC issues the ethical clearance to the PI. The ERC should take note of the changes in the protocol based on the NCIP review, if any. If the changes are not acceptable, the ERC should initiate a dialogue with the NCIP. The NCIP has the final say with regard to socio-cultural and traditional aspects of the study.

**6.8 Filing of protocol-related documents and updating of the Protocol Database**

Protocol documents are filed in the protocol file folder which. The new protocol will be logged in the protocol database.

## 7. FORMS AND TOOLS

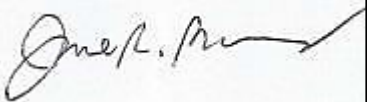

Endorsement Letter to NCIP  
Approval from NCIP Authority

## 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:
		
<b>ETHICS REVIEW COMMITTEE</b>	<b>DR. JANE R. BORRINAGA, MD, FPCP</b> ERC Chair	<b>EXUPERIA B. SABALBERINO, MD, MPH, CEsE</b> EVHRDC Executive Committee Chair
Date: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022