Eastern Visayas Health Research and Development Consortium- Ethics Review Committee (EVHRDC-ERC) STANDARD OPERATING PROCEDURE CHAPTER 2: INITIAL REVIEW PROCEDURES		
MANAGEMENT OF INITIAL SUBMISSIONS	SOP No.	05
	Version No.	06
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

Application for Ethical Review is standardized, systematic, and is accepted only when documents are complete and appropriate after proper screening by the ERC Staff Secretary. The cut-off date to receive protocols for review is every 15th day of the month. Administrative meetings and full review are regular meetings which occur on the same date, every second Friday of the other month. If the date falls on a holiday it will be conducted on the third Friday. Expedited primary review meeting occurs on the last Tuesday of the month.

2. OBJECTIVE/S OF THE ACTIVITY

The activity aims to ensure consistency, efficiency, and transparency in the application for ethical review.

3. SCOPE / APPLICABILITY

The activity guides all applications for ethical review coming from researchers of different institutions involving human participants.

- Member and non-member institutions conducting research in Region 8.
- Protocols referred by the Single Joint Review Ethics Board (SJREB) to be submitted by Sponsor / PI or its representative where Region 8 is one of the sites of a multicenter research ***(See SOP No. 09 Single Joint Research Ethics Board Review Process).***

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the researcher/institution. Evaluation of completeness of documents is the responsibility of the ERC Member Secretary and ERC Staff Secretary.

ERC Staff secretary – receives, determines the completeness, and acknowledges receipt of documents, and provide a code for the protocol package.

Principal Investigator - submits the application and pertinent documents.

ERC Chair – Conducts preliminary review to determine the type of review (exempt from review, expedited review, full board review)

5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Submission of complete documents	Principal Investigator	15th day of the month
Step 2: Acknowledge receipt	ERC Staff Secretary	3 days from cut-off date
Step 3: Determine the type of review	ERC Chair	
Step 4: Designate primary reviewers	ERC Chair	
Step 5: Prepare the protocol package for distribution to the Primary Reviewers	ERC Staff Secretary	7 days from cut-off date
Step 6: Filing of initial protocol package in a properly labeled protocol folder	ERC Staff Secretary	7 days

6. DESCRIPTION OF PROCEDURES

6.1 Submission of complete documents

The Principal Investigator (PI) must accomplish the **Form 5.1 Protocol Package Checklist, Form 5.2 Application for Initial Protocol Review, Form 5.3 Protocol Summary**, **Form 5.4 Non-disclosure Agreement** and attach the three (3) copies of the research proposal together with an e-copy sent to the EVHRDC ERC email, 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.

All protocols (both electronic and hardcopy) shall be submitted on or before the 15th day of the month.

- The schedule of the full board review is every 2nd Friday of the other month.
- The expedited Primary Reviewer (PR) review is scheduled every last Tuesday of the month.

The ERC Staff Secretary checks the completeness of the submitted documents using **Form 5.1 Protocol Package Checklist** and will only accept the documents if complete. Documents to be completed are as follows:

- ☐ Form 5.1 Protocol Package Checklist
- ☐ Form 5.2 Application for Initial Protocol Review
- ☐ Form 5.3 Protocol Summary
- ☐ Form 5.4 Non-disclosure Agreement (Principal Investigator)
- ☐ Application for Review – Request Letter addressed to the ERC Chair
- ☐ Study Protocol
    - ☐ Title
    - ☐ Significance of the study
    - ☐ Literature Review
    - ☐ Project Duration
    - ☐ Objectives of the study
    - ☐ Methodology & Procedures
    - ☐ Description of the study population
    - ☐ Exclusion/inclusion criteria
    - ☐ Data analysis
    - ☐ Dummy tables
    - ☐ Work Plan Schedule (Gantt chart)
    - ☐ Ethical considerations (which include, but not limited to)
        - ☐ Disclosure of Conflict of Interest
        - ☐ Confidentiality and Data Protection Plan (in compliance with Data Privacy Act)
        - ☐ Vulnerability Issues
        - ☐ Risk/Benefit Statement
        - ☐ Mitigation of Risk
        - ☐ Research Dissemination Plan
- ☐ Schematic Diagram/Conceptual Framework
- ☐ Gantt Chart for Schedule of activities
- ☐ Study Protocol Budget/Line-Item Budget
- ☐ Supplementary Documents (if applicable)
        - ☐ Questionnaire
        - ☐ Data Collection Forms
        - ☐ Product Brochure/Basic Product Information Document (for Phase IV clinical trials)
        - ☐ Permit/s for Special Population (please specify)

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☐ Informed Consent Forms *(preferably using the WHO template with a statement that EVHRDC-ERC reviewed the protocol and includes its contact information for possible queries and complaints from the participants (053 888-4203)*

☐English ☐ Vernacular ☐Others

☐ Assent Form (if applicable)

☐English ☐ Vernacular ☐Others

☐ Technical Review Certificate

☐ Curriculum Vitae for all members of the Study Team

☐ Proof of Payment of Initial Review Fee, if applicable

☐ Three (3) hardcopies of the study protocol

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. In the absence of the chair, the Vice-chair or member secretary may determine the type of review. The types of review are as follows:

6.3.1 **Full Review** – for protocols that entail more than minimal risk to participants or those that involve vulnerability issues.

6.3.2 **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 stores tissues or date. Requires at least 2 reviewers, one (1) scientist and one (1) non-scientist.

6.3.3 **Exempt From Review** – for protocols that neither involve human participants nor identifiable human tissue, biological samples, and data.

6.4 Designate primary reviewers

The ERC Chair designates at least two ERC members to be the primary reviewers of the protocol regardless of whether the type of review is expedited or full board.

- Primary reviewers are selected on the basis of expertise related to the protocol.
- The medical/scientific reviewer analyzes the scientific and ethical aspects of the protocol using the Protocol Evaluation Form and also

looks into the ethical issues in the ICF and process while the non-scientist member focuses on the ICF and informed consent procedure using the Informed Consent Evaluation Form.

- If the ERC membership does not have the needed expertise, the ERC Chair chooses from the roster of Independent Consultant ***(see SOP No. 03 Appointment of Independent Consultants)***.

6.5 Prepare the protocol package for distribution to the Primary Reviewers

The ERC Staff secretary prepares the protocol package to be distributed to the Primary reviewers. The timeline from the receipt of the complete package to the distribution is within 7 working days.

6.6 Filing of initial protocol package in a properly labeled protocol folder

The ERC Staff secretary files a copy of the protocol package in the active file cabinet with a properly labeled protocol file folder with code on the side of the folder. The details are logged in the protocol database.

7. FORMS AND TOOLS

Form 5.1	Protocol Package Checklist
Form 5.2	Application for Initial Protocol Review
Form 5.3	Protocol Summary
Form 5.4	Non-disclosure Agreement
Form 28.1	Submission Log
Form 28.2	Study Protocol Database
Protocol Package	

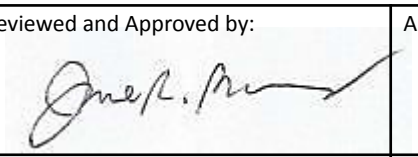
8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	12/05/2012	ERC	First draft
2	10/23/2015	ERC	Updates on procedures
3	12/05/2019	ERC	Adopt recommendation from PHREB CSA
4	10/18/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco	Updates on procedures and policy.

		Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	
5	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	Revised description of procedures and added timeline in the Workflow
6	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 Mr. Raymond G. Campo	Added the following under Ethical Considerations: Vulnerability Issues, Risk/Benefit Statement, and Mitigation of Risk

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