Eastern Visayas Health Research and Development Consortium- Ethics Review Committee (EVHRDC-ERC) STANDARD OPERATING PROCEDURE CHAPTER 2: INITIAL REVIEW PROCEDURES		
EXEMPT FROM REVIEW	SOP No.	08
	Version No.	02
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

Research protocols that present no more than minimal risk or harm are exempted from either full review or expedited review.

Study protocols may be exempted from ethical review based on the criteria listed in the 2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017) The Research Ethics Review Process Guideline 3.1. The decision to exempt from review rests on the ERC Chair for efficiency and in the interest of time. Study protocols that may be exempted are:

- Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols).
- Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests.
- Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
    - There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.
    - The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
    - Protocols that involve the use of publicly available data or information.

Decisions to exempt must be documented and reported to the full board. Protocols that qualify for exemption are automatically archived and reclassified as INACTIVE, and protocol records will be made available for three (3) years from date.
Study protocols granted exemption are likewise exempt from further review including progress and continuing review. The ERC must be notified for modifications that will

significantly affect the previous risk-benefit assessment or qualification for exemption, in which case it may be submitted as a new protocol for initial review.
The ERC must be provided with a copy of the Final report not later than one (1) month from the end of study.

2. OBJECTIVE/S OF THE ACTIVITY

To describe the ERC activity for the review of protocols that qualify for exemption from review.

3. SCOPE AND APPLICABILITY

This applies to study protocols submitted to the ERC that qualifies for exemption from review.

4. ROLES AND RESPONSIBILITIES

ERC Chair - is responsible for the assessment whether the submitted protocol qualifies for exemption from review.

Principal Investigator - report changes in the protocol that may cause revocation of the exempt granted or cause reclassification of the type of review.

ERC Staff Secretary - communicates the decision to the Principal Investigator/s.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Submission of research protocol	Principal Investigator
Step 2: Evaluation of exempt criteria	ERC Chair
Step 3: Preparation of Certificate of Exemption	ERC Staff Secretary
Step 4: Communicate decision to the Principal Investigator	ERC Staff Secretary
Step 5: Inclusion of the report on the next full board meeting	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 Submission of research protocol

The Principal Investigator (PI) submits and attaches 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.

6.2 Evaluation of exempt criteria

The ERC Chair or a designated ERC member who does not have any conflict of interest should review the study protocol applying for review exemption. The ERC Chair or the designated ERC member evaluates the study protocol using the Exemption Criteria using **Form 8.1 Checklist for Exemption from Ethical Review**. If the protocol does not meet the Exemption Criteria, the protocol is reclassified and follows ***SOP No. 06 Full Review*** or ***SOP No. 07 Expedited Review.***

6.3 Preparation of Certificate of Exemption

The ERC staff secretary prepares **Form 8.2 Certificate of Exemption from Ethics Review** and forwards it to the ERC Chair for signature.

6.4 Communicate decision to the Principal Investigator

The staff secretary communicates the decision to the PI and sends **Form 8.2 Certificate of Exemption from Ethics Review**.

6.5 Inclusion of the report on the next full board meeting

The staff secretary includes the protocol that received the certificate of exemption from ethics review in the agenda of the next meeting for reporting purposes.

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

The ERC Staff Secretary prepares a binder that contains all protocols that were exempted from review. He/she files the properly-labeled binder in the appropriate shelf of the storage cabinet and updates the protocol database for exemption from review.

7. TOOLS/FORMS

Form 8.1	Checklist for Exemption from Ethical Review
Form 8.2	Certificate of Exemption from Ethics Review

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	12/05/2019	ERC	First Draft

2	11/25/2022	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.

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