



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

CHAPTER 1: STRUCTURE AND COMPOSITION

APPOINTMENT OF INDEPENDENT CONSULTANTS	SOP No.	03
	Version No.	01
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

The ERC shall maintain a roster of Independent Consultants who may be called upon when their expertise is needed for study protocols under review. He/she need not be affiliated with the institution. The ERC Chair determines the external expertise requirements and sends invitations, upon prior approval of the EVHRDC Chair, to various professionals with specific scientific expertise to be part of the EVHRDC ERC representing expertise not present in the current committee composition.

The independent consultants will have a term of 3 years and are renewable for another term (3 years) depending on the need of his/her expertise based on the prevailing needs of the specific research topics reviewed by the EVHRDC ERC. The independent consultants are not considered a member of the ERC and do not have any voting privilege.

2. OBJECTIVE/S OF THE ACTIVITY

Describe the procedure of the appointment of ERC independent consultants.

3. SCOPE / APPLICABILITY

This SOP describes the procedure for engaging the services of a professional expert as a consultant to the EVHRDC ERC. If the ERC Chair determines the study procedures that are not within the area of competence of any ERC members, the ERC Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the ERC.

4. ROLES AND RESPONSIBILITIES

ERC Chair – recommends the names of independent consultants to the EVHRDC Chair
EVHRDC Chair – approves invitation letters and appointment of independent consultants upon the advice or recommendation of any ERC member, the ERC Chair

recommends the names to the EVHRDC Chair for his/her appointment as independent consultant. It is the responsibility of the ERC Chair and members to determine the need of independent consultants due to the lack of expertise and facilitate its appointment.

Independent Consultant – reviews are focused on:

- Scientific procedures and methodology
- Any new information about the disease/research topic and the proposed Interventions
- Benefits and Risks of the intervention and how to mitigate the risks
- The consultant must complete the assessment form to be reviewed by the ERC at the time the study is reviewed.
- The consultant may attend the ERC meeting, present his/her assessment, and participate in the discussion but without the right to vote. The report becomes a permanent part of the study file.
- The consultant will be given an honorarium.
- Consultant’s services may be terminated by either the consultant or by the EVHRDC Chair. Upon termination of the consultant’s services, the ERC Staff Secretary shall ensure that all the necessary documentation related to the Independent Consultant is filed with the other administrative documents.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: The committee determines the need of an independent consultant	ERC Chair
Step 2: Preparation of documents	ERC Staff Secretary
Step 3: Sending of Invitation Letters	ERC Staff Secretary
Step 4: Signing of documents	Independent Consultants
Step 5: Filing of documents and documentation	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 The committee determines the need of an independent consultant

Considering the nature of the protocol for review the Chair and members identify the expertise needed that the ERC membership do not have. The ERC Chair submits the name of the independent consultant to the EVHRDC Chair.

6.2 Preparation of documents

The ERC Staff Secretary prepares the letter of invitation, that includes the following; Terms of Reference, duration of the consultation with the general overview of deliverables and honorarium. The ERC Staff Secretary also requests a copy of the consultant's Curriculum Vitae using **Form 1.2 Curriculum Vitae**.

6.3 Sending of Invitation Letters

- The ERC Staff Secretary sends the letter to the independent consultant using **Form 3.1 Letter of Invitation to Independent Consultants** after it is signed by the ERC Chair together with a copy of **Form 1.4 Confidentiality Agreement and Conflict of Interest Disclosure**.

6.4 Signing of documents

The ERC Staff Secretary asks the independent consultant to sign **Form 1.3 Appointment with Terms of Reference** and **Form 1.4 Confidentiality Agreement and Conflict of Interest Disclosure**. The independent consultants will have a term of 3 years and are renewable for another term (3 years) depending on the need of his/her expertise based on the prevailing needs of the specific research topics reviewed by the EVHRDC ERC.

6.5 Filing of documents and documentation

The ERC Staff Secretary organizes and completes the documents in the independent consultant files. The ERC Staff Secretary creates one file for each independent consultant. The independent consultant file should include:

- **Form 1.2 Curriculum Vitae**
- **Form 1.3 Appointment with Terms of Reference**
- **Form 1.4 Confidentiality Agreement and Conflict of Interest Disclosure**
- **Form 3.1 Letter of Invitation to Independent Consultants**

7. FORMS AND TOOLS

Form 1.2	Curriculum Vitae
Form 1.3	Appointment with Terms of Reference
Form 1.4	Confidentiality Agreement and Conflict of Interest Disclosure
Form 3.1	Letter of Invitation to Independent Consultants

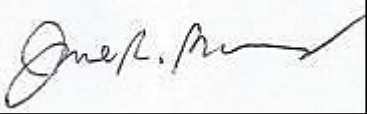

8. HISTORY

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	First draft

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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