Form 1.3 Appointment with Terms of Reference

**Eastern Visayas Health Research and Development Consortium - Ethics Review Committee**

***APPOINTMENT WITH TERMS OF REFERENCE***

**Date:**

Name

Department and Position

Institution

Dear \_\_\_\_\_\_\_\_\_\_\_\_\_\_:

In line with your nomination as the Eastern Visayas Health Research and Development Consortium- Ethics Review Committee (EVHRDC-ERC), we are pleased to appoint you as the Ethics Review Committee (ERC) *Chair/ Member* of the said committee with the following duties and responsibilities, to wit:

 *(Mention the responsibilities stated in TOR Section IV. Roles and Responsibilities)*

As the *chair/ member* of the committee, you will be entitled to an honorarium per meeting depending upon the amount stated in the Approve Line Item Budget and the availability of funds for the project. You will also be entitled to claim travel expenses and allowances for your attendance to trainings and other EVHRDC and/or ERC activities. Please find attached Terms of Reference.

This appointment is valid from mm/dd/yyyy to mm/dd/yyyy.

If you agree to these terms, please sign in the spaces below:

Conforme:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Very truly yours,

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Designating Officer

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Eastern Visayas Health Research and Development Consortium

**ETHICS REVIEW COMMITTEE**

**TERMS OF REFERENCE**

1. Role/ Purpose

The role of the Eastern Visayas Health Research and Development Consortium –Ethics Review Committee (EVHRDC-ERC) are the following:

* + - * 1. Issue ethical clearance for researches reviewed and approved for scientific and ethical acceptability for locally, nationally and internationally implemented research in the region;
				2. Review amendments/ changes in the protocol of researches previously approved;
				3. Ensures application of ethical standards in research, monitors progress reports; and
				4. Ensures responsiveness of proposals to health needs and priorities of the region.

Based on WHO Operational Guidelines for Ethics Committee, the Ethics Review Committee (ERC) is responsible for *“acting in the full interest of potential research participants and affected communities, taking into the account the interests, needs of the researchers, and having due regard for the requirement of relevant regulatory agencies and applicable laws.”*

1. Terms

This Term of Reference is effective from **(start date)** and continues until **(completion date)** or will be ongoing until terminated by agreement between the parties.

1. Membership

1. The committee is composed of a Chair and at least 6 members of which representation may come from the following discipline/ sector:

* 1. Doctor of Medicine/Health Researcher
	2. Religious Sector
	3. Environmental Scientist/ Engineer
	4. Legal Practitioner
	5. Social and Behavioral Scientist/ Researcher
	6. Public Health
	7. Layperson/ *probationary member*

The chair and members of the ERC is officially endorsed by the institutional head to the consortium through a release of Special Order.

The above composition considers age balance and gender equality.

2. Committee members will cease to be a member if they will:

Resign from the committee;

Fail to attend 3 consecutive meetings without providing valid excuse to the chairperson;

Resign from their employment; and

Breach confidentiality

3. Any vacant position/s will be filled by the institution the previous member was affiliated with .

1. ROLES and RESPONSIBILITIES OF MEMBERS

i. The ERC Chair is appointed by the EVHRDC Chair and is accountable for:

1.1 Presiding the conduct of the committee meeting according to the agenda and time available;

1.2 Facilitating the review of proposals for ethical consideration/s;

1.3 Facilitating the monitoring and the evaluation of ethically approved researches;

1.4 Facilitating the preparation of planned activities of the committee;

1.5 Assigning tasks to the members of the committee on issues/ matters/ topics pertinent to the committee’s concern;

1.6 Coordinating with the other committees of EVHRDC on matters affecting/ related to the ethics committee;

1.7 Coordinating with the EVHRDC ERC Staff Secretary in the implementation of activities and report preparations and financial management of the committee; and

1.8 Overseeing the programs of the committee.

ii. The ERC Vice-Chair is elected by the committee and is accountable for:

 2.1 Performs the task of the committee chair in events where she is unavailable;

2.2 Regularly attending the committee meeting as scheduled by the committee Chair;

2.3 Reviewing of proposals for ethical concerns;

2.4 Assisting the chair in monitoring and evaluation of ethically approved researches;

2.5 Facilitating tasks assigned by the committee chair corresponding to the issues/ matters/ topics pertinent to the committee’s concern;

2.6 Assisting the chair in coordinating with the EVHRDC ERC Staff Secretary in the implementation of activities and report preparations and financial matters; and

2.7 Assisting the chair in overseeing the programs of the committee.

iii. The ERC Member-Secretary is elected by the committee and is accountable for:

3.1 Supervises the ERC Members related to good ERC office management

3.2 Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair

3.3 Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting

3.4. Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions,

3.5. Supervises the ERC Members in the preparation of the meeting agenda and minutes

3.6. Supervises the ERC Members in the preparation of the annual report of the ERC to be submitted to PHREB.

3.7. Ensures good ERC documentation and archiving

3.8. Ensures overall ERC compliance with good clinical practice.

iv. The Lay (Non-medical/non-scientific) is elected by the committee and is accountable for:

4.1 The lay (non-medical or non-scientific) member of the ERC focuses on the human subject/participant concerns and reviews the informed consent process and the informed consent forms to ensure adequate and proper application of international and national principles and guidelines.

4.2. The primary role of the non-medical, non-scientist member is to share his or her insights about the communities from which participants will be drawn and about the informed consent process and form.

4.3. Regularly attending the committee meeting as scheduled by the committee Chair;

4.4. Reviewing of proposals for ethical concerns;

4.5. Assisting the chair in monitoring and evaluation of ethically approved researches;

4.6. Facilitating tasks assigned by the committee chair corresponding to the issues/ matters/ topics pertinent to the committee’s concern;

4.7. Assisting the chair in coordinating with the EVHRDC ERC Staff Secretary in the implementation of activities and report preparations and financial matters; and

4.8. Assisting the chair in overseeing the programs of the committee.

v. The MEMBERS is elected by the committee. His/her responsibilities include the following:

* 1. Regularly attending the committee meeting as scheduled by the committee Chair;
	2. Reviewing of proposals for ethical concerns;
	3. Assisting the chair in monitoring and evaluation of ethically approved researches;
	4. Facilitating tasks assigned by the committee chair corresponding to the issues/ matters/ topics pertinent to the committee’s concern;
	5. Assisting the chair in coordinating with the EVHRDC ERC Staff Secretary in the implementation of activities and report preparations and financial matters; and
	6. Assisting the chair in overseeing the programs of the committee.

vi. The COMMITTEE is expected:

 6.1 To be able to review researches to be done by local, national, and international researchers to be implemented in the region;

 6.2 To be able to issue ethical clearance to health researchers reviewed and approved;

 6.3 To be able to ensure that the researches are relevant to the health needs and priorities of the region;

1. MEETINGS, TRAININGS AND OTHER ACTIVITIES

* + - * 1. The committee meets regularly every other month;
				2. Holding of special meeting will be upon the discretion of the chair;
				3. A quorum is declared if attendee in the meeting is composed of half of total number of members plus one;
				4. Members of the ERC undergoes continuing training on the ethics and science of biomedical research and other relevant capability building activities;
				5. The committee Chair has the right to endorse a representative from the committee to attend local and national activities the committee has been invited in case, he/she can’t make it;
				6. As an output, training/ event representative submits an activity report to the EVHRDC ERC Staff Secretary.

1. Reference

EVHRDC ERC Standard Operating Procedure (SOP) Manual