



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

GENERAL INFORMATION	SOP No.	00
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ERC VISION

A Leader of Quality and Ethically Sound Health Researches in Eastern Visayas.

ERC MISSION

To ensure all health and health related researches conducted in Region 8 shall comply with the national and international ethical standard for research.

ERC HISTORY

The Philippine Council for Health Research and Development of the Department of Science and Technology (PCHRD-DOST), with its thrust of developing and encouraging research activities, and in the interest of equity, organized the Regional Health Research and Development Committee (RHRDC) in several regions.

With the DOH handling the RHRDC 8 ERC secretariat function, it was in the year 1982 that the Ethics Review Subcommittee was organized as one of the four (4) subcommittees of the RHRDC 8. The three (3) other subcommittees are namely: Research Management Subcommittee, Resource Management Subcommittee, and Research Information Subcommittee.

Specifically, the main function of the newly organized Ethics Review Subcommittee were to undertake ethical review of health related proposals in the region and to conduct monitoring and evaluation on implemented and ongoing projects of the RHRDC 8. Initially, the Ethics Review Subcommittee was composed of one (1) Chairman and four (4) members.

In the year 1988, the RHRDC ERC Secretariat's functions was transferred to the DOST regional offices. The activities of the committee were directed towards updating health research priorities, training of research manpower, and screening of research protocols.

The RHRDC was revitalized on July 1994, after its operation has been stopped for quite a time, to provide control, direction, leadership and coordination on matters related to

health research development and promotion geared towards optimizing results in order to accelerate economic and social development Region.

Like any other RHRDCs, EVHRDC became the structure through which PCHRD's Institution Development Programs were implemented and became the mechanism that encouraged and promoted health research activities in Region VIII. It should be able to formulate/disseminate the regional and national health agenda, develop/review research proposals (technical and ethical aspects), implement projects, disseminate research results, develop and manage databases of researches/researchers mobilize resources of member agencies (networking) and manage RHRDC/EVHRDC activities.

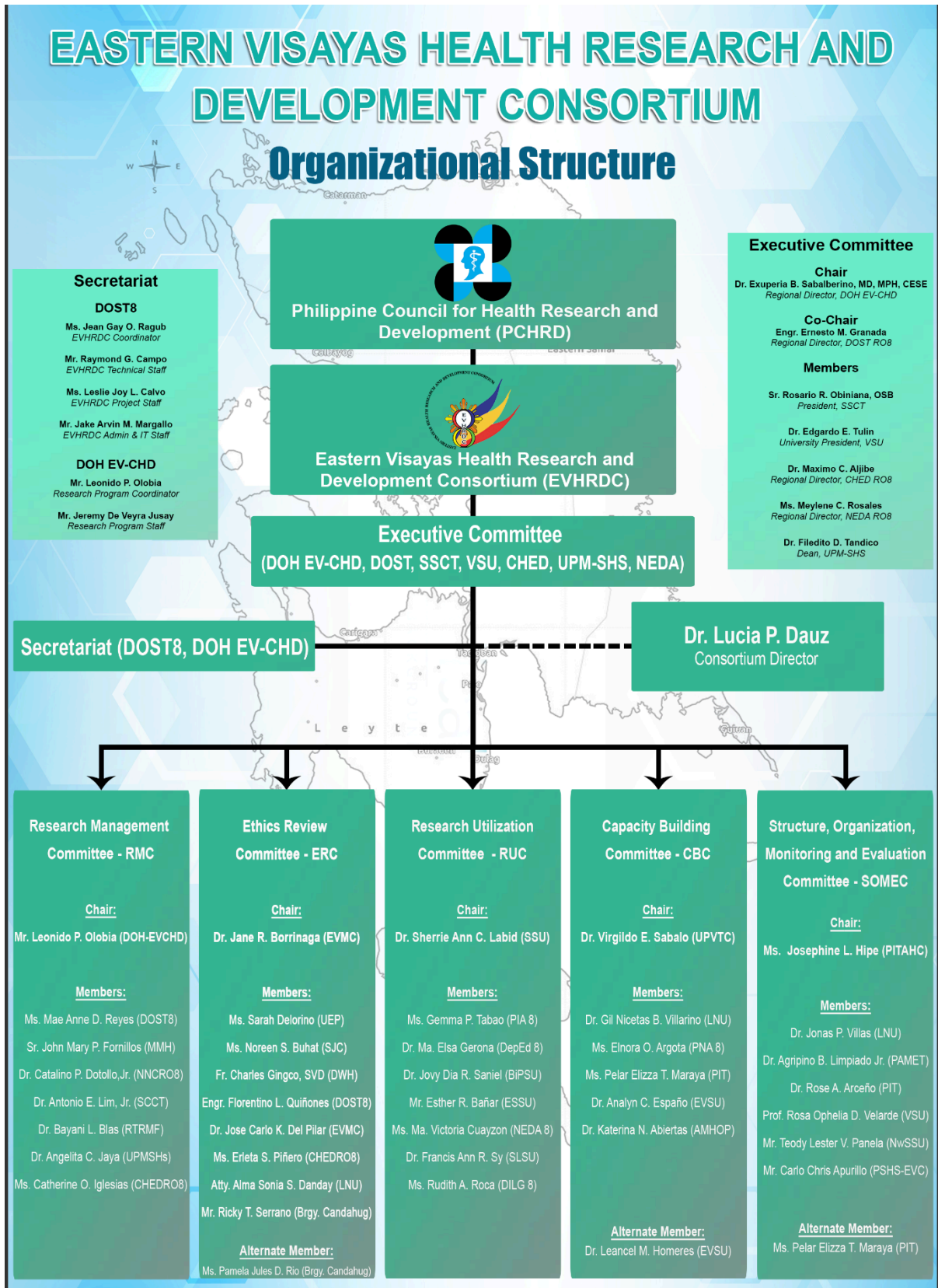
In 2009, the committee adopted the name Eastern Visayas Health Research and Development Consortium. With this, the status of the Ethics Review Subcommittee was elevated to Ethics Review Committee (ERC). At present, the EVHRDC ERC is a Level II Philippine Health Research Ethics Board (PHREB) accredited, composed of one (1) chair and eight (8) members.

EVHRDC ERC MANDATE

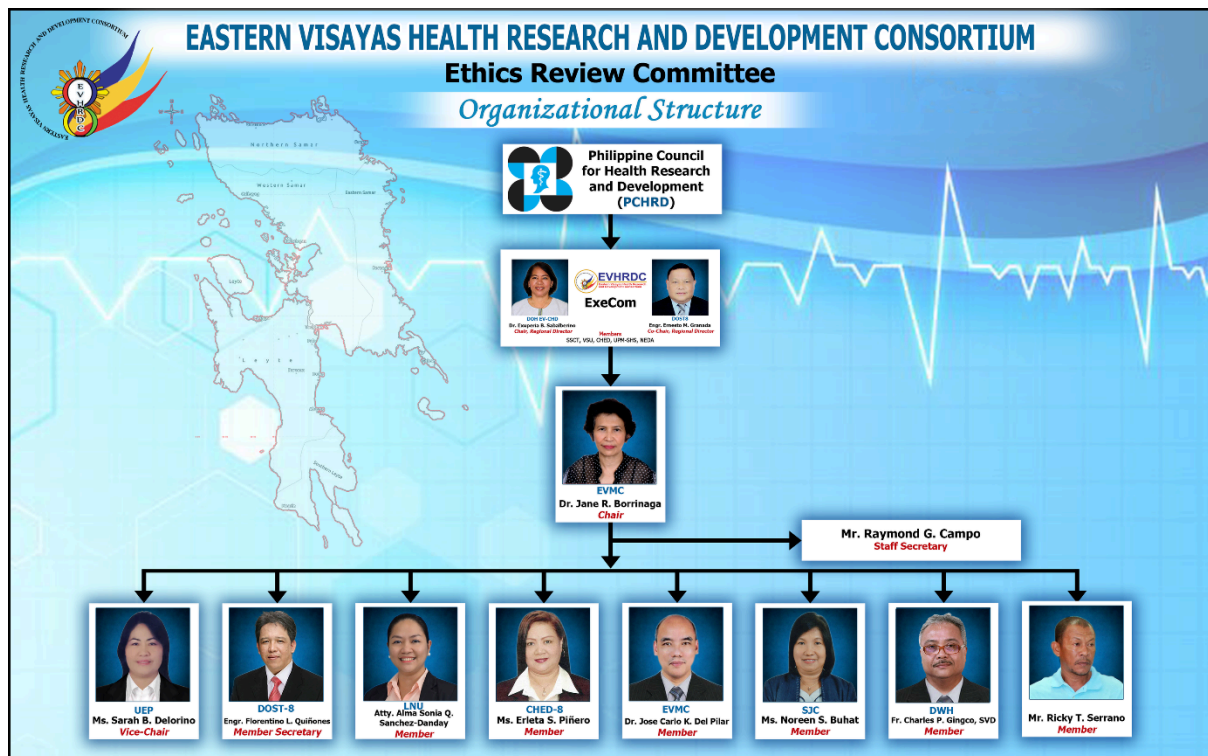
The EVHRDC ERC commits for the protection and safety, well-being and autonomy of participants in any health research conducted in Region 8. Towards this end, the independence and impartiality of the committee is guaranteed. The EVHRDC ERC review and monitor health researches that involve:

- EVHRDC ERC reviews health related research protocols conducted by member institutions and/or non-member institutions (State University and Colleges, Hospitals, National Government Agencies and other foreign entities/institutions) in Region 8.
- Researches conducted in Region 8 by EVHRDC member institutions with no accredited Research Ethics Committee.
- EVHRDC ERC may review researches referred from the PNHRs, PHREB, DOH, SJREB, industry organizations, and other academic institutions to be conducted in Region 8.

EVHRDC ORGANIZATIONAL STRUCTURE



EVHRDC-ERC ORGANIZATIONAL STRUCTURE



ERC FUNCTIONS AND RESPONSIBILITIES

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.”

Functions

- Evaluate the conduct of research in the region in accordance with the international and national guidelines, local laws, standards of professional conduct and practice, community morals, values and needs;
- Promote research integrity by identifying and resolving conflicts of interests;
- Establish appropriate mechanisms in all stages of the research in order to:
 - Ensure the safety, protect the rights, and promote the welfare and well-being of research participants
 - Provide counsel to research participants, including proponents and researches
 - Ensure prompt reporting of changes in the protocol and unanticipated problems.

- Ensure the proper documentation of and adherence to the confidentiality rule and policy on informed consent.
- Monitor the progress of the ongoing research.
- Report to the institutional or national authorities any matter that affects the conduct and ethics of research which in its view may affect the rights and safety of research participants;
- Keep a systematic and organized record of all proposals reviewed, including actions taken and other pertinent information; and
- Submit annual report to PHREB through DOST-PCHRD, which contains the following:
 - Composition of ERC (name, educational attainment, recent ethics training/ seminars attended) and term of office;
 - Members of the ERC, Staff Secretary, office and email addresses and contact numbers;
 - Number of meetings per year (date and venue)
 - Number of researches reviewed during the year
 - ☐ Researches approved without changes
 - ☐ Researches for which ERC required modifications or revisions before approval
 - ☐ Researches disapproved

ERC MEMBERSHIP

COMPOSITION

- The committee is composed of a Chair and eight (8) members of which representation comes 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. Non-scientist/non-institutional/*probationary member*
- A probationary member, who is a leader of a concerned population of the study, is considered.
- The above composition considers the age balance and gender equality.

APPOINTMENT

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

- The EVHRDC Chair is the appointing official of the ERC. The appointing official indicates in his/her appointment paper the functions, term of office, scope of work, conditions of appointment, and honorarium.
- Procedures for the renewal of appointment, resignation, replacement, grounds for disqualification, and procedures in regard to conflict of interest due to financial gains is included in the manual of operating procedures of the consortium and the EVHRDC ERC Standard Operating Procedures.
- The members shall be appointed and serve for a period of three (3) years, renewable every three (3) years unless the EVHRDC member institution opt to change its representative.

As a regular member:

- ☐ Each member of the ERC signs a disclosure document which states that he/ she has no conflict of interest (e.g. financial interests in a pharmaceutical company) and observes the “no contact rule” policy as a reviewer, as well as sign of confidentiality agreement.

As an independent consultant:

- ☐ The consortium, in coordination with the ERC chair/authorized member, establishes a list of independent consultants, which would include the consultants’ special expertise regarding ethical, scientific, physiological or social aspects for research, which will be updated as the need arises.
- ☐ In the deliberation of a research study involving special participant groups or concerns (e.g. HIV, AIDS, physically challenged), the chair invites an advocate coming from the list of independent consultants.

ERC ROLES

- Reviews of scientific merit and ethical acceptability of any research submitted to EVHRDC involving human participants.
- Research approved by the national or foreign ERC for implementation in the region is to be subjected to the ethics review.
- Ensures that the ethical standards applied of a foreign research to be implemented in the country are no less stringent than they would be if the research were to be carried out in the country of the sponsoring agency.
- Monitors the study progress of the research.
- Ensure the responsiveness of the proposed research to the health needs and priorities of Eastern Visayas and it meets the requisite ethical standards (CIOMS, 2002).
- Issues ethical clearance required for the implementation of the reviewed and approved research.
- Review amendments/ changes in the protocol of researches that have been previously approved.

Meetings

1. The committee meet regularly every 2nd Friday of the other month.
2. Expedited Primary Reviewer Meeting is scheduled on the last Tuesday of each month.
3. Holding of a special meeting will be upon the discretion of the chair.
4. A quorum is declared if the attendees in the meeting are composed of half the total number of members plus one, with the inclusion of a non-scientist and non-affiliated member.

Trainings

- Members of the ERC undergoes continuing training on the ethics and science of biomedical research and other relevant capability building activities.
- Initial training must be required of new members. Continuing educational activities must be held at least once a year.