



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

CHAPTER 1: STRUCTURE AND COMPOSITION

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| TRAINING OF ERC MEMBERS AND STAFF | SOP No. | 04 |
| | Version No. | 01 |
| | Version Date | 11-28-2022 |
| | Effective Date | 01-01-2023 |

1. STATEMENT OF POLICY

The National Ethical Guidelines for Health and Health-Related Research mandates that all ERC members shall undergo initial and continuing training on the ethics and science of health-related research. It is the responsibility of all EVHRDC ERC members and staff to undergo training during the course of their appointment and to continuously update themselves and train on relevant knowledge and skills. The EVHRDC ERC Chair shall enjoin all members and staff to attend training/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development.

Therefore, the Eastern Visayas Health Research and Development Consortium is responsible for allocating an annual budget for specific training and other educational activities for EVHRDC ERC members and staff.

2. OBJECTIVE/S OF THE ACTIVITY

This SOP shall ensure that ERC members and staff are provided appropriate training in order to capacitate them in the conduct of a competent and efficient ethical review.

3. SCOPE AND APPLICABILITY

This SOP applies specifically to the process of providing training to ERC members and staff. This SOP begins with the provision for training and ends with the filling of training records of ERC members in the membership file.

4. ROLES AND RESPONSIBILITIES

Compliance shall be the responsibility of the ERC Chair, ERC Members, and ERC Staff Secretary

EVHRDC Chair - allocates the budget for training based on the approved Work and Financial Plan.

ERC Chair - Identify and set the training requirements of the members and staff.

ERC Staff Secretary - files and updates the training records of the officers and members.

5. WORKFLOW

| ACTIVITY | RESPONSIBILITY |
|--|-----------------------------------|
| Step 1: Set training requirements | ERC Chair |
| Step 2: Find available trainings, seminars, lectures or workshops | ERC Chair |
| Step 3: Signify intention to attend training or Chair instructs member/s to attend | ERC Members, ERC Staff Secretary |
| Step 4: Process travel documents | EVHRDC Chair, ERC Staff Secretary |
| Step 5: Attend training and keep training record | ERC Members, ERC Staff Secretary |
| Step 6: Store and update training record in ERC membership file | ERC Staff Secretary |

6. DESCRIPTION OF PROCEDURES

6.1 Set training requirements

The ERC Chair periodically reviews compliance with training requirements for ERC members and staff. The following are required courses:

- Basic Research Ethics and Good Clinical Practice (GCP) (initial mandatory training)
- Standard Operating Procedures (initial mandatory/in-house training)
- Continuing Ethics Education
- Relevant laws and regulations
- Relevant developments in science, health and safety, and other educational activities on international trends including international specialist's meetings organized for the exchange of experiences and information.

6.2 Find available trainings, seminars, lectures or workshops

The ERC Chair gets information about training courses, workshops, conferences, etc., which are periodically announced on websites, and various media channels and selects the most appropriate training.

6.3 Signify intention to attend training or Chair instructs member/s to attend

Once an offered training has been identified, the ERC Chair, ERC member or staff files request for possible participation and request for funds to cover registration fees and travel allowances. **Form 4.2 Training Referral Request** is accomplished and submitted with supporting documents, including but not limited to confirmation of registration and training program at least one (1) month before the training date. The ERC Chair recommends and endorses the participation to the EVHRDC Chair for his/her final action.

6.4 Process travel documents

A letter request to travel and provision of training and travel funds are prepared by the ERC staff secretary with supporting documents and forwarded to the EVHRDC Chair or EVHRDC Co-chair for approval. Once approved, the official letter is forwarded to the identified participant's head of institution.

6.5 Attend training and keep training record

The ERC member or staff attends the training and submits proof of attendance to the ERC Chair, such as Certificate of Participation/Appearance/Attendance and official receipt for paid training courses. Attendees are encouraged to echo their experiences and learnings during regular monthly meetings.

6.6 Store and update training record in ERC membership file

The ERC staff secretary updates the **Form 4.1 Training Record** of the attending member to document the attendance in training in chronological order and the training database. A copy of the Participation/Appearance/Attendance is filed in the ERC membership file. The Staff Secretary updates the training monitoring record.

7. FORMS AND TOOLS

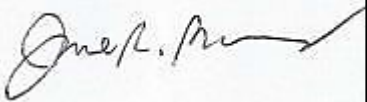

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| Form 4.1 | Training Record |
| Form 4.2 | Training Referral Request |

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 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 | First draft |

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

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| 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 |