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| **Eastern Visayas Health Research and Development Consortium-<br>Ethics Review Committee (EVHRDC-ERC)<br>STANDARD OPERATING PROCEDURE<br><br>CHAPTER 3: POST APPROVAL PROCEDURES** | | |
| **EARLY STUDY TERMINATION APPLICATION** | SOP No. | 17 |
| | Version No. | 03 |
| | Version Date | 11-28-2022 |
| | Effective Date | 01-01-2023 |

## 1. STATEMENT OF POLICY

All research protocols reviewed and approved by the committee recommended for early termination are reported to EVHRDC ERC for approval of the termination. The Principal Investigator (PI) needs to report the proposed termination date, participants enrolled to date, summary of the results to date, and the reason for termination with justification.

Researches may be terminated early or prematurely because of various reasons, such as poor participant recruitment, frequent occurrence of adverse reactions, insufficient funding, etc. In these cases, early protocol termination may be recommended by the Data Safety Monitoring Board (DSMB), the scientific director, the sponsor, the PI, the ERC itself, and/or other authorized bodies. A plan for early termination shall include reason/s for termination and also strive to ensure the safety and privacy of already recruited participants. Applications for early termination shall undergo full board review.

## 2. OBJECTIVE/S OF THE ACTIVITY

To review early termination reports and decide on how to proceed with the termination plan, with primary consideration on the safety and well-being of recruited study participants and adherence to the principles of fairness for all parties concerned.

## 3. SCOPE / APPLICABILITY

This policy applies to the review of early termination reports. This SOP begins with the receipt of the application or recommendation for early termination and documentation in the logbook, and ends with the documentation of the final early termination report and updating of the database.

## 4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the principal investigator (PI), ERC Staff Secretary and the ERC Members.

**Principal Investigator** - Submits the form for Early Study Termination with other protocol related documents.

**ERC Staff Secretary** – determines the completeness and acknowledges receipt of documents.

**ERC Chair** - Identify the primary reviewers.

## 5. WORKFLOW

| ACTIVITY | RESPONSIBILITY |
|---|---|
| Step 1: The Principal Investigator submits the early study termination application | Principal Investigator |
| Step 2: Check approval given by ERC from the protocol files and collect relevant information | Primary Reviewers |
| Step 3: Review the termination package and make recommendations | Primary Reviewers |
| Step 4: Discuss with full board for appropriate decision | Primary Reviewers, ERC Members |
| Step 5: Communicate ERC decision | 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 The Principal Investigator submits the early study termination application

Application or recommendation for early termination may also be submitted by the DSMB, the scientific director, the sponsor, the ERC itself, and/or other authorized bodies shall be received by the ERC staff secretary and documented in the logbook. The PI is informed to prepare and submit a protocol termination package. After submission of the package by the PI, it is checked for completeness by the ERC Member Secretary. The package should include the following:

- **Form 17.1 Early Study Termination Report**
- **Form 14.2 Progress Report**, up until application for early termination
- The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data

### 6.2 Check approval given by ERC from the protocol files and collect relevant information

The primary reviewers of the approved protocol or a designated ERC member studies the retrieved protocol files and acquires other information pertinent to the study, particularly its current status.

### 6.3 Review the termination package and make recommendations

The primary reviewers/designated ERC members conduct a full review of the contents of the early termination protocol package, and make recommendations on how study termination will be carried out. Of primary importance are the safety data for participants that have already been recruited, as well as a plan that includes steps and procedures on how the safety and well-being of these participants can be ensured moving forward.

### 6.4 Discuss with full board for appropriate decision

The ERC shall discuss the protocol in a full board meeting. After taking into consideration all comments and recommendations from all members present in the meeting, the decision may be one of the following:

- Acceptance of the decision for termination without further question or action
- Request for additional information regarding the application for termination

The staff secretary prepares a draft of the full board decision based on the minutes of the meeting, which will then be signed by the ERC Chair.

### 6.5 Communicate ERC Decision

After the committee makes a decision on the early termination of the protocol and officially signed by the ERC Chair, the staff secretary informs the PI of this decision within seven (7) working days.

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

The ERC Staff Secretary keeps copies of the finalized early termination report for documentation and updates the database accordingly.

## 7. FORMS AND TOOLS

Form 14.2 Progress Report
Form 17.1 Early Study Termination Report

## 8. HISTORY

| Version No. | Date (mm/dd/yyyy) | Authors | Main Change |
|---|---|---|---|
| 1 | 10/23/2015 | ERC | First Draft |
| 2 | 12/05/2019 | ERC | Updates on procedures and policy. |

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| 3 | 11/28/2022 | Dr. Jane R. Borrinaga<br>Ms. Sarah B. Delorino<br>Engr. Florentino L. Quiñones<br>Ms. Noreen S. Buhat<br>Fr. Charles Gingco<br>Dr. Jose Carlo K. Del Pilar<br>Ms. Erleta S. Piñero<br>Atty. Alma Sonia Q. Sanchez-Danday<br>Mr. Ricky T. Serrano<br>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**<br>ERC Chair | **EXUPERIA B. SABALBERINO, MD, MPH, CESe**<br>EVHRDC Executive Committee Chair |
| Date: 11-28-2022 | Date: 11-28-2022 | Date: 11-28-2022 |