	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	**SOP 4. MANAGEMENT OF POST APPROVAL SUBMISSION 4.3 Review of Early Termination**	Effective Date: January 02, 2019

Supersedes:	Previous SOPs
Prepared by:	SOP Team 2019
Reviewed by:	Dr. Manuel Emerson Donaldo
Reviewed Date:	December 14, 2018
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Date Approved	December 20, 2018
Date Effective:	January 2, 2019

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1. Policy Statement

Researchers shall report the early termination of a study that has been previously approved by the IRB. The report shall include a comprehensive discussion on the reasons why such decision was reached.

2. Objective of the Activity

This activity describes how the IRB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study.

3. Scope

This SOP starts with the reporting of early termination of a study, and ends with filing of the pertinent documents.

4. Responsibility

It is the responsibility of the IRB to act on any early protocol termination report as decided or recommended upon by the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, PI, by the IRB itself. It is the responsibility of the IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at full board for appropriate action. The Secretariat is responsible for the receipt and management of the termination documentation. The primary reviewers review the reasons for early termination and make a recommendation to full board.

5. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1:*Receive the application or recommendation for early termination*	*Primary Investigators, IRB Secretariat, Members*
Step 2: *Retrieval of pertinent protocol file*	*IRB Secretariat*
Step 3*: Notification of Chair and Primary Reviewers*	*IRB Secretariat*
Step 4: *Inclusion of report in the agenda of the next REC regular meeting (SOP on Preparing the Meeting Agenda-SOP#5.1)*	*IRB Secretariat*
Step 5:*Discuss at Full Board for appropriate decisions*	*Primary Reviewer, Chair*
Step 6: *Communication of decision to the Principal Investigator/researcher (SOP on Communicating IRB Decisions-SOP#6.2)*	*IRB Secretariat*
Step 7: *Filing of all related documents (SOP on Managing Active Files (SOP #7.2)*	*IRB Secretariat*

6. Description of Procedures

Step 1: *Receive the report for early termination (Form 4.3)*

- Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, PI, by the IRB itself or other authorized bodies.
- The Secretariat shall receive the application and document the submission in the log book.
- The secretary should require the [progress/continuing Review report together with the early termination Report.

Step 2: *Retrieval of pertinent protocol file*

- The IRB Secretariat shall retrieve the protocol from the Active Files to determine the identity of primary reviewers

Step 3: *Notification of Chair and the Primary Reviewers*

- The IRB Secretariat shall notify the Chair and the Primary Reviewers of the report through SMS and a phone call within48 hours from submission.

Step 4: *Inclusion of report in the agenda of the next IRB regular meeting (SOP on Preparing the Meeting Agenda-SOP#5.1)*

- The IRB Secretariat shall prepare the report to be presented in the IRB meeting

Step 5: *Discuss at Full Board for appropriate decisions*

- All applications for early termination of a study are reviewed at full board for appropriate action. Reason/s for the early termination is/are presented for possible appropriate action.

Step 6: *Communication of decision to the Principal Investigator/researcher (SOP on Communicating IRB Decisions- SOP#6.2)*

- The Secretariat takes shall take note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI. (SOP on Communicating IRB Decisions SOP #6.2)

Step 7: *Filing of all related documents (SOP on Management of Active Files - SOP# 7.2)*

- The IRB shall file all the documents, to include the submitted reports, and IRB decision in the Active File. (SOP on Managing Active Files SOP #7.2)

7. Forms

ANNEX 1. Form 4.3 Early Termination Form

8. History

Version No.	***Date***	***Authors***	***Main Change***
1	*Nov. 16, 2019*	*SOP Team*	*First Draft*

9. References

- International Ethical Guidelines for Health-related Research Involving Humans Council for International Organizations of Medical Sciences (CIOMS) 2016
- Philippine Health Research Ethics Board (PHREB) Workbook 2015
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- Chong Hua Hospital Institutional Review Board SOPs http://chonghua.com.ph/irb/SOP.html

ANNEX 1

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EARLY STUDY TERMINATION APPLICATION FORM

Form 4.3

IRB Ref. No:		Sponsor Protocol No.	
Protocol Title:			
Principal Investigator:			
Phone:		Email:	
Department:			
Sponsor:			
IRB Approval Date:		Date of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	
Reasons for early termination Summary of Results			
Accrual Data: How many have completed the study? How many are still active? Plans for those who are still active in the study			
P.I. Name & Signature:		Date:	

For IRB Use

Assessment by the Primary Reviewer (any issue related to participant safety?)

Recommendations:

Final IRB decision:
Date of full board meeting: