



Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 22.0 Review of Early Protocol Termination

Effective Date:
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PCMC IR-EC SOP 22.0: Review of Early Protocol Termination

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22.0 REVIEW OF EARLY PROTOCOL TERMINATION

22.1 Policy Statement

Early protocol termination may be a decision by the researcher or by the sponsor. The IR-EC shall review cases of application for early termination (researcher) or a report of early termination (sponsor). The focus of review shall be on the justification and management of participants who have been recruited.

22.2 Purpose of the Activity

The review of early protocol termination aims to secure the safety of participants and ensure appropriate management of resources.

22.3 Scope

This SOP includes the procedures in reviewing early protocol termination that begins from the receipt of the application for early study termination and ends with the filing of pertinent documents.

22.4 Process Flow/Steps for Review of Early Protocol Termination

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Receipt of application for early study termination	IR-EC Secretariat
2	Forwarding the Notice of Early Termination to the Chair and Primary Reviewers	IR-EC Secretariat, Chair
3	Deliberation during full board meeting	IR-EC Members
4	Communicating the IR-EC decision to PI	IR-EC Chair, Secretariat
5	Filing pertinent documents and updating the protocol database	IR-EC Secretariat

22.5 Detailed Instructions

22.5.1 Receipt of application for early study termination

22.5.1.1 An application for early termination shall be submitted when an IR-EC approved study is being recommended for termination before its scheduled completion. This is done when the rights, safety and welfare of the participants are threatened or upon the request of the PI or sponsor due to operational problems.



- 22.5.1.2** The following are reasons for researcher-initiated early protocol termination:
- failure to recruit subjects
 - lack of funding
 - health reasons
 - safety issues in the site study
 - observed high risk to the participants
 - health reasons
- 22.5.1.3** The following are justifications for sponsor-initiated early protocol termination:
- loss of communication from the PI or non-reporting of the PI
 - loss of confidence with PI / misconduct of PI
 - failure to recruit
 - high risk assessment and data safety monitoring recommendation
 - completion of required target sample population.
- 22.5.1.4** The recommendations for early termination may come from the Sponsor, the Data Safety Monitoring Board (DSMB), IR-EC Members, or other authorized/regulatory bodies.
- 22.5.1.5** The Secretariat shall receive the study protocol termination package prepared and submitted by the Principal Investigator.
- 22.5.1.6** The Secretariat shall check the completeness of the contents of the package to include the Protocol Code number and Early Study Termination Form (IR-EC Form 22.1) The request for termination memorandum shall contain a brief written summary of the protocol, its results and accrual data.
- 22.5.1.7** The Secretariat shall check approval given by the IR-EC and the type of review from the protocol data base.

22.5.2 Forwarding the Notice of Early Termination to the Chair

- 22.5.2.1** The Chair shall review the termination package for termination issues and make recommendation. He/She shall review the safety data. It is Important for the termination package to contain a plan to follow up the participants who shall still be active in the study.
- 22.5.2.2** The IR-EC secretariat shall include the review of the study for early termination in the meeting agenda for full board review.

22.5.3 Deliberation during full board meeting

- 22.5.3.1** The Chair shall present the early study termination application with his recommendation during a full board meeting. The Members shall discuss and deliberate for appropriate decision.



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- 22.5.3.2** Final decision of the application are as follows:
- a. Acknowledged
 - b. Further information required

22.5.4 Communicating the IR-EC decision to PI

- 22.5.4.1** The Secretariat shall prepare the Notification Letter – Early Study Termination for signature of the IR-EC Chair. The Secretariat shall communicate the PCMC IR-EC decision to the PI through a letter approved and signed by the Chair.
- 22.5.4.2** The PI may be requested to provide additional information or documents or implement actions to ensure the safety and welfare of subjects still active in the study.

22.5.5 Filing pertinent documents and updating the protocol database

- 22.5.5.1** The IR-EC Secretariat shall file the following in the protocol file folder: the Early Study Termination report, excerpts of the minutes of the meeting when the report was discussed and the Notification Letter in the protocol file folder and shall update the protocol file index.
- 22.5.5.2** Upon approval of the Early Study Termination application, the study protocol shall be classified as inactive, the Protocol Code number is updated and the protocol file folder shall be re-labeled and transferred to the storage cabinet for inactive files.
- 22.5.5.3** The IR-EC Secretariat shall update the protocol database and labels the protocol “inactive-early termination”.

22.6 Forms

Form 22.1 V.3.0 Study Termination Form

22.7 Glossary