
	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 14/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 14. Review of Early Termination Report	

Supersedes:	02
Version:	03
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	(Adapted from UPMREB SOP and 2020 PHREB SOP Workbook)
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14.1. Policy Statement

An early study termination shall be submitted when a study approved by the UPCHE REC is being recommended for termination before its scheduled completion. This is done when the safety of the study participant is at risk and also upon the request of the Principal Investigator or the sponsor due to the existence of unresolvable valid complaints. Early termination reports shall undergo full review.

14.2. Objective

Review of early termination reports aims to ensure fairness for all concerned parties and that the decision takes into consideration the safety and welfare of study participants that have already been recruited.

14.3. Scope

This SOP begins with the receipt and entry to the logbook of the early study termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database.

14.4. Workflow for Review of Early Termination Report (12 to 19 working days)


	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Receipt of early termination report and related documents	Administrative Secretary	1
2	Notification of the Chair and Primary Reviewers	Administrative Secretary	2
3	Review of the report (SOP 7)	Primary Reviewer and Members	7 to 14
4	Communication of the REC decision	Chair and Administrative Secretary	1
5	Filing of document and updating of protocol database	Administrative Secretary	1

*working days

14.5. Description of Procedure

14.5.1. Receipt of early termination report and related documents:

The Administrative Secretary receives the accomplished Form 32 [Early Termination Report] and logs the information on Form 12 [Submissions Log].

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The Administrative Secretary retrieves the protocol folder and summarizes the documents that have been submitted.

14.5.2. Notification of the Chair and Primary Reviewers:

The Administrative Secretary informs the Chair and the Primary Reviewers about the report and the summary of documents that have been submitted.

14.5.3. Review of the report:

- a. The Administrative Secretary includes the report in the agenda of the next meeting and ensures that the Primary Reviewer is given the necessary documents to prepare the presentation during the next meeting (SOP 7 Full Review).
- b. The committee deliberates on the implications on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection, termination plan for enrolled participants and dissemination of specific information to the study participants. The Chair calls on the Members to recommend any of the following actions:
 - Acceptance of the decision with no further action
 - Request information (specify the needed information from the PI/RP)
 - Recommend further action (specify the required action from the PI/RP)

14.5.4. Communication of REC decision:

- a. The Administrative Secretary notifies the PI/RP of the decision on the early study termination report through an action letter (Form 26 or Form 42 Archiving Notification).
- b. The Chair approves, signs and dates the letter. Refer to SOP 21: Communicating REC Decisions.


14.5.5. Filing document and updating of protocol database:

The Administrative Secretary files the early study termination report and a copy of the REC decision in the appropriate protocol folder. The protocol database is also updated accordingly.

14.6. Forms

The following forms are used in the implementation of this SOP:


- Form 12: Submissions Log
- Form 26: Action Letter – Request Information

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- Form 32: Early Study Termination Form
- Form 42: Archiving Notification

14.7. Document History

Version No.	Date	Authors	Main Change(s)
01		Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	First draft
02	04 December 2020	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section.
02	27 October 2022	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Asst. Prof. Kristyn T. Caragay Mr. Edgar G. Belda Jr. Mary Anne Ramos-Tumanan, Ph.D. Assoc. Prof. Rowena Grace R. Sanchez Fredelyn G. Tolete	Revised the SOP right header box to include a simplified SOP code and added date of approval
02	18 July 2023	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Ma. Leonora dL Francisco, Ph.D. Adelaida V. Mayo, Ph.D. Marian Michelle D. Navales Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Added timeline (in working days) for each step in the Workflow Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement) Changed from SOP 13 to SOP 14 after SOP on Review of Progress Report was added to the SOPs for post approval.
03	13 March 2024	Prof. Emeritus Maria Patricia V. Azanza Mary Anne Ramos-Tumanan, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Ma. Leonora dL Francisco, Ph.D. Adelaida V. Mayo, Ph.D. Edgar G. Belda Jr. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Added details in the Review of Report step. The Committee will also review the provisions for the termination plan for enrolled participants.

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03	08 July 2024	See updated list of authors	Updated the list of authors to include all regular members following the change in membership of the UPCHE REC. Added "termination plan for enrolled participants" in 14.5.3b.
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