
	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 24/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 24. Archiving of Documents	

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Authored by:	<div> Mary Anne R. Tumanan, Ph.D. Cecile Klaudine C. Cabigas, RND Joanne R. Bantang, Ph.D. Merilyn Barrameda B. Berdin Kristyn T. Caragay Ma. Leonora dL Francisco, PFT, Ph.D. Maria Asuncion M. Hije John Limwelle P. Lectura, RPm Loriezel P. Lectura Adelaida V. Mayo, Ph.D. Charla Rochella S. Saamong Sofia Belen A. Sarte Ronilyn M. Tamayo, RND Casiana Blanca J. Villarino, PFT, Ph.D. </div> <div> Maria Fema S. Aquino, Ph.D. Airisae Rae P. Basinang, PFT Consuelo T. Chua, Ph.D. Miriam I. Ugaddan Josephine Louise F. Jamero Maria Josephine T. Lumawig Michael A. Magcamit Darwin M. Malabanan Jin Mark D.G. Pagulayan, PFT Joseph G. Taluban Jr. Maria Carmela C. Taob, RND Lorena W. Tengco, RND Fredelyn G. Tolete </div> <div> <p><i>Previous REC Members:</i></p> <div> Maria Patricia V. Azanza, Ph.D. Cecile Leah T. Bayaga, Ph.D. Lilibeth J. Baylosis Edgar G. Belda Jr. Kathleen Keisha R. Constantino Bless Lorraine T. Desabelle </div> <div> Johanna Victoria A. Faustino Marian Michelle D. Navales Maria Monica E. Rayala Rowena Grace R. Sanchez Rev. Fr. Jose S. Tupino III </div> </div>
	(Adapted from UPMREB SOP and 2020 PHREB SOP Workbook)
Endorsed by:	Mary Anne R. Tumanan, Ph.D. Chair, UPCHE REC
Date:	
Approved by:	Shirley V. Guevarra, Ph.D. Dean, College of Home Economics University of the Philippines Diliman
Approval Date:	

UNIVERSITY OF THE PHILIPPINES COLLEGE OF HOME ECONOMICS
RESEARCH ETHICS COMMITTEE
Rm 217, 2nd Floor, College of Home Economics
Ma. Regidor St, UP Diliman, Quezon City 1101
Telephone: +63 2 9818500 local 3407; Email: upcherec.upd@up.edu.ph

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24.1. Policy Statement

Study files which have been terminated or completed or declared inactive shall be kept in a separate storage for three (3) years. The following studies shall be archived:

1. Completed study with an REC approved final report
2. Protocols with approved early study termination reports
3. Studies of researchers who have not resubmitted their proposals within 3 months after receiving the Notification Letter (considered inactive).

24.2. Objective

Archiving of inactive, terminated, or completed protocols aims to ensure efficient retrieval of information from the files for compliance with national and international guidelines and for reference.

24.3. Scope

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.


24.4. Workflow for Archiving (4 working days)

	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Acceptance of final/early termination report and identification of inactive protocols	Chair, Member Secretary, and Members	1
2	Notification of the Principal Investigator/research proponent (PI/RP)	Administrative Secretary	1
3	Updating the protocol folder	Administrative Secretary	1
4	Transfer of protocol folder in the archives and updating the protocol database	Administrative Secretary	
5	Access to active or inactive files	Administrative Secretary	1

**working days*

24.5. Description of Procedure

24.5.1. Acceptance of final/early termination report and identification of inactive protocols:

	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 24/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 24. Archiving of Documents	

- a. The Committee Members approve or accept the final report or early termination report during a meeting (SOP 14 Review of an Early Termination Report; SOP 15: Review of Final Report).
- b. In the identification of an Inactive File, the Administrative Secretary informs the Member Secretary of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the REC in the last 3 months during which time the researcher/proponent/investigator has been appropriately reminded of the requirement.

This is included in the agenda of the next meeting where the protocol is declared inactive.

Archived (Exempted/Inactive/Completed/Terminated) study files are:

- Study protocols exempted from ethics review,
- Study protocols with approved (by the UPCHE REC) final reports or early termination reports,
- Study protocols declared Inactive by the review if no communication is received from the study team for a period of three months.

24.5.2. Notification of the PI/RP:

- a. Upon determination that a study protocol file is inactive or upon approval of a final report or early termination report, the Administrative Secretary notifies the PI/RP using Form 33 [Action Letter – Final Report Approval] or Form 42 [Archiving Notification].
- b. The Chair signs the archival notification prior to sending to the concerned PI/RP.

24.5.3. Updating the protocol folder:


- a. The Administrative Secretary files the Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.
- b. The Administrative Secretary codes the protocols to be archived by adding the year of archiving to the original code of the study file, e.g., 2022-0001-2023.

24.5.4. Transfer of protocol folder in the archives and updating the protocol database:

- a. The Administrative Secretary checks whether documents listed in the protocol file index are complete and removes unnecessary copies of the documents.
- b. The Administrative Secretary also updates the protocol database and transfers the protocol folder to the archive section.

24.5.5. Access to active or inactive files

- a. Active or inactive study files can be borrowed, upon written request by the PI/RP or the UPCHE REC Chair, and only for room use. Only authorized UPCHE REC

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	SOP 24. Archiving of Documents	

Administrative Secretary can retrieve documents either from active study files or from the archives.

- b. The Administrative Secretary places the borrower's information in a file folder using Form 39 [Borrowers Log] and contains the following information:
- Study file code
 - Date when borrowed
 - By (borrower)
 - Signature of borrower
 - Date when returned
 - Signature of Administrative Secretary upon return of document


24.6. Forms

For this SOP, the following form(s) were utilized:

- Form 33: Action Letter – Final Report Approval
- Form 39: Borrowers Log
- Form 42: Archiving Notification

24.7. 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	18 November 2022	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Marian Michelle D. Navales Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Revised the SOP right header box to include a simplified SOP code and added date of approval
02	10 August 2023	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay	Added timeline (in working days) for each step in the Workflow

	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 24/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 24. Archiving of Documents	

		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	Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement) Changed from SOP 23 to SOP 24 after SOP on Review of Progress Report was added to the SOPs for post approval.
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.