
	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 08/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 8. Management of Resubmissions	

Supersedes:	02
Version:	03
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> <i>Previous REC Members:</i> 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>
	(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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8.1. Policy Statement

The REC shall require resubmission of a study protocol that requires either minor or major modification/s within four (4) weeks upon receipt of the REC decision letter. For protocols initially classified under expedited review, minor and major modifications shall undergo expedited review during resubmission. For protocols initially classified under full board review, major modifications shall undergo full review but minor modifications shall undergo expedited review during resubmission.

8.2. Objective

Organized management of study protocol resubmission aims to ensure that the principal investigator/research proponents (PI/RP) addressed the required modifications before approval of the protocol.


8.3. Scope

This SOP pertains to the resubmission of revised or modified study protocols that were reviewed by the REC. The procedure begins with the receipt of the revised protocol documents and ends with filing of the documents in the protocol file and the entry of the submission in the protocol database.

8.4. Resubmission Review Workflow (12 to 21 working days)

	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Receipt of revised study protocol package	Administrative Secretary	1
2	Coding and logging of the resubmitted protocol	Administrative Secretary	1
3	Notification of the Chair and the Primary Reviewers	Administrative Secretary	2
4	Review of the resubmitted study protocol package a. Expedited Review (SOP 6) b. Full Review (SOP 7)	Primary Reviewers	5 to 14
5	Communication of REC decision	Administrative Secretary	2
6	Filing of documents in the Protocol File and updating the database	Administrative Secretary	1

**Working days*

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8.5. Description of Procedure

8.5.1. Receipt of revised study protocol package:

- a. The Administrative Secretary receives the resubmitted study protocol documents, checks the nature of the document and ensures completeness using Form 10 [Review Checklist].
- b. The Administrative Secretary also checks the version number of the resubmitted revised protocol and Informed Consent Form. For traceability, version number shall be added to the UPCHE REC code provided for the protocol with the format: YYYY-NNNN ver. XX. For example, a protocol with a code of 2020-0001 will have an updated code of 2020-0001 ver. 02 if it has been resubmitted.

8.5.2. Coding and logging of the resubmitted protocol:


The Administrative Secretary indicates the code assigned to the protocol when it was initially submitted and stamps the date of receipt on the documents. The submission is properly logged into Form 12 [Submissions Log] for proper documentation.

8.5.3. Notification of the Chair and the Primary Reviewers:

- a. The Administrative Secretary retrieves the decision letter (Form 16 or 17) that pertains to the resubmitted protocol and informs the Chair about the resubmission and about the nature of the modifications required from the researcher.
- b. Given the necessary information, the Chair determines the type of review of the resubmitted protocol - for minor modifications, by expedited review (SOP 6) or the Chair can review and decide at his/her level and for major modifications, by full review (SOP 7).
- c. The Chair directs the Administrative Secretary to inform the reviewers concerned and to forward to them the necessary documents.

8.5.4. Review of the resubmitted study protocol documents:

- a. The primary reviewers that were assigned at the initial submission of a protocol will also review the revised version of the protocol. The assigned reviewers conduct review of the resubmitted protocol by referring to Form 18 [Review of Resubmitted Study Protocol] noting the different recommendations made by the REC and evaluating whether these were satisfactorily addressed in the revised protocol.
- b. The reviewers submit the accomplished forms and report to the Secretariat within 5 to 14 working days after receipt of the resubmitted protocol. The Administrative Secretary informs the Chair.
- c. The Secretariat includes the resubmitted protocol in the agenda of the next regular meeting.

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8.5.5. Communication of REC decision:

- For Resubmissions approved at the level of the Chair: Chair dictates his/her decision to the Administrative Secretary for preparation of the draft letter, finalization and sending to the researcher.
- For the resubmissions that underwent Full Review, refer to SOP 20: Communicating REC Decisions. Form 16 or Form 28 may be used to communicate the decision to the PI/RP.

8.5.6. Filing of documents and updating of protocol database:

The Administrative Secretary files all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter) and enters the relevant information on resubmission in the appropriate protocol database.


8.6. Forms

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


- Form 08: Study Protocol Assessment Form
- Form 09: Informed Consent Assessment Form
- Form 10: Review Checklist
- Form 12: Submissions Log
- Form 16: Action Letter – Approval of Protocol
- Form 17: Action Letter – Modification of Protocol
- Form 18: Review of Resubmitted Protocol Form
- Form 28: Action Letter – Protocol Resubmissions/Amendments

8.7. 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	20 Nov 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	Responsibilities: The responsibility of deciding the appropriate review type for resubmission of protocols is now shared by the Chair, REC discipline expert (which may also be the same as Primary Reviewer), and a non-affiliate

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			<p>member. Initially, only the Chair was tasked to decide the type of review for resubmissions.</p> <p>Workflow: Added time frame for relevant procedures-earliest within 2 working days to notify the reviewers, earliest within 3-7 days to communicate REC decision to PI/RP</p> <p>Description of Procedures: 1. Added the format for notation of the version number of resubmitted protocols: YYYY-NNNN ver. XX. 2. Added the correct forms to be used in communicating REC decisions to PI/RP.</p> <p>Forms: Added Form 28: Action Letter – Protocol Resubmissions/Amendments to the list of forms.</p> <p>References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section.</p> <p>Revised the SOP right header box to include a simplified SOP code and added date of approval</p>
02	06 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	<p>Added timeline (in working days) for each step in the Workflow</p> <p>Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement)</p>
03	01 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	<p>Revised detail for procedure Filing of Documents in item 8.5.6.</p>

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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. Stated in 8.5.6. "The Admin. Sec. files all the pertinent..."
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