
	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 11/03 Approval Date: 18-Nov-2024 Effective Date: 18-Nov-2024
	SOP 11. Protocol Amendment Review	

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

The UPCHE REC shall require the submission of applications for protocol amendment for any changes involving the study protocol and/or informed consent documents. Favorable approval should be obtained from the REC prior to the implementation of an amendment.

11.2. Objective


This activity aims to ensure that the safety and welfare of study participants are protected during the implementation of a study through systematic review of any modifications made to previously approved study protocols.

11.3. Scope

This SOP applies to the management of an application for protocol amendment submitted by the proponent while the study is still on-going. This SOP begins with the receipt of applications for protocol amendment and ends with the entry to logbook and protocol database.

11.4. Workflow for Protocol Amendment Review (14 to 25 working days)

	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Receipt and logging submission of protocol amendment submission	Administrative Secretary	1
2	Notification of the Chair and the Primary Reviewers	Administrative Secretary	2
3	Classification of submission	Chair, Member Secretary, Primary Reviewers	3
4	Review of the submitted study protocol amendment documents a. Expedited Review (SOP 6) b. Full Review (SOP 7)	Primary Reviewers	Full review: 7 to 14 Expedited review: 5 to 10
5	Inclusion of protocol amendment for full review and report on expedited review in the agenda of the next meeting	Chair and Administrative Secretary	1
6	Communication of REC decision	Administrative Secretary	1 to 3 after receipt of recommendations
7	Filing of documents and updating of protocol database	Administrative Secretary	1

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**working days*

11.5. Description of Procedure

11.5.1. Receipt and logging of protocol amendment submission:

The Administrative Secretary receives the submitted Form 22 [Study Protocol Amendment Form] of the PI/RP or his/her representative and logs the date of submission on Form 12. The submission shall also include the approval or endorsement of the relevant technical panel/committee. Include a statement indicating whether the amendments are considered major or minor.

The Administrative Secretary retrieves the originally approved protocol file and these are sent to the Chair and Primary Reviewers for guidance and reference.


11.5.2. Notification of the Chair and the Primary Reviewers:

The Administrative Secretary notifies the Chair and Primary Reviewers regarding the submission. The initially approved protocol file and the received Form 22 are provided to the Chair as reference for the classification of review.

11.5.3. Classification of submissions:

The Chair, Member Secretary, and the primary reviewer/s classify protocol amendment review as expedited or full review based on the following:

AMENDMENTS	
EXPEDITED REVIEW	FULL REVIEW
Proposed protocol amendments that have minor modifications and no significant risk to study participants, such as: <ul style="list-style-type: none"> Administrative revisions, such as correction of typing errors Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc. Research activity includes only minor changes from previously approved protocol. Minor protocol amendments that do not change the risk/benefit assessment. 	<ul style="list-style-type: none"> Major revisions of the protocol and informed consent after initial review. Amendments that involve major changes from previously approved protocol or consent form Major amendments that change the risk/benefit ratio Change in study design that increases risk to study participants which may include but is not limited to: <ul style="list-style-type: none"> Additional treatments or the deletion of treatments Any changes in inclusion/exclusion criteria Change in method of dosage formulation, (e.g., oral changed to intravenous) Significant change in the number of subjects, and Significant decrease or increase in

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	dosage amounts
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11.5.4. Review of the submitted study protocol amendment:

- As a general rule, the original Primary Reviewers during Initial Review serve as Primary Reviewers of protocol amendments. The Chair assigns an alternative reviewer if an original Primary Reviewers is unavailable to accomplish the review or has ceased to be a member of the UPCHE REC.
- Reviewers focus the review on the effect of the amendment on the feasibility of the study to continue, safety and well-being of participants and overall risk-benefit ratio and the need for re-consent of the study participants.
- Protocol amendment by expedited review – The Primary Reviewers accomplish the Form 22 and return it to the Administrative Secretary earliest within 5 to 10 working days. Action is finalized at the level of the Chair earliest within three (3) working days upon receipt of recommendations by the Primary Reviewers for expedited reviews – approval, minor or major modifications or disapproval.
- After review by primary reviewers, the protocol for full review is included in the agenda of the next REC meeting.

11.5.5. Inclusion of protocol amendment for full review and report on expedited review in the agenda of the next meeting:

The Chair instructs the Administrative Secretary to include in the next REC meeting Agenda (SOP 18: Preparation for a Meeting) the protocol amendment for full review and the report on expedited review of protocol amendment.


Decision on the protocol amendment

- Approval
- [Request for additional information](#)
- [Recommend further action](#)
- Disapproval

11.5.6. Communication of REC decision:

The Administrative Secretary notifies the PI/RP of the decision on the protocol amendment through an action letter (Form 27 or 28) within 1 to 3 working days after receipt of the recommendations. Refer to SOP 22: Communicating REC Decisions.

11.5.7. Filing of documents and updating of protocol database:

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The Administrative Secretary files the protocol amendment documents and a copy of the REC decision in the appropriate protocol folder. The protocol database is also updated accordingly.


11.6. Forms

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

- Form 12: Submissions Log
- Form 22: Study Protocol Amendment Form
- Form 27: Approval Letter for Protocol Amendment
- Form 28: Action Letter for Protocol Resubmission

11.7. 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	27 October 2022	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 G. Tolete	References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section. Revised the SOP right header box to include a simplified SOP code and added date of approval Details of Procedure: Itemized steps 6.4 and 6.5 to clarify procedures for expedited and full review of protocol amendments
02	13 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.	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)

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		Fredelyn G. Tolete	Changed from SOP 10 to SOP 11 after SOP on Review of Progress Report was added to the SOPs for post approval.
03	08 July 2024	See updated list of authors	<p>In 11.5.1., added requirements for protocol amendment: approval or endorsement of the relevant technical panel/committee and a statement whether the amendment is major or minor.</p> <p>Updated the process to include the Member Secretary in the Classification of Submissions step.</p> <p>Updated the list of authors to include all regular members following the change in membership of the UPCHC REC.</p> <p>Updated the decision points for protocol amendments.</p>