
	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 06/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 6. Expedited Review	

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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6.1. Policy Statement

An expedited review shall be conducted for study protocols that

1. do not pose more than minimal risk to the study participants
2. do not involve vulnerable populations
3. do not generate vulnerability to the participants
4. do not involve collection of stigmatizing information or cause stigmatization of study participants
5. use anonymized or archived samples

Expedited review is also conducted for continuing review of studies previously classified under expedited review. Minor protocol deviations/violations and protocol study protocol amendments that are administrative in nature and do not affect the safety and risk/benefit to study participants can also be classified under expedited review.

The results of the initial review shall be released to principal investigator/research proponent (PI/RP) within four (4) weeks after the submission of complete requirements. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting. Protocols with modifications required shall be revised by the proponent and resubmitted for REC review. Disapproved protocols shall be referred for full review of REC. If the protocol is also disapproved by the Committee after the full review, proponent may appeal to the REC by submitting a letter containing the justification for the appeal addressed to the Chair (see SOP 28 Management of Appeals).

6.2. Objective


Expedited review aims to ensure appropriate and effective systems are used for the protection of human participants in research.

6.3. Scope

This SOP applies to initial and post-approval submissions of protocols which have been classified accordingly under expedited review. This SOP begins with the accomplishment and submission of the evaluation forms by the assigned Primary Reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting.

6.4. Expedited Review Workflow (13 to 18 working days)

	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Assignment of reviewers	Chair	1
2	Notification of the reviewers	Administrative Secretary	1
3	Provision of documents and evaluation forms to reviewers	Administrative Secretary	1

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4	Accomplishment and Submission of evaluation forms	Reviewers	5 to 10
5	Finalization of the review results	Reviewers, Chair	2
6	Communication of review results to the PI/RP	Secretariat	1
7	Filing of documents in the protocol file folder updating the protocol database	Administrative Secretary	1
8	Inclusion of the Review Report in the Agenda of the next REC regular meeting	Secretariat**	1

**Working days; **Secretariat – Member Secretary and Administrative Secretary*

6.5. Description of Procedure

6.5.1. Assignment of reviewers:

- Once determined that the study satisfies any of the criteria to be classified for Expedited Review, the Chair assigns 2 reviewers – a scientist member to assess the scientific/technical and ethical soundness of the study and a non-scientist member to assess the informed consent process and the informed consent form (or assent form).
- If there are no REC members with the field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review.
- Post-approval review of required reports that qualify for expedited review will be conducted by the original reviewers, unless they are not available and another reviewer is assigned by the Chair.


6.5.2. Notification of the reviewers:

The Administrative Secretary notifies the assigned reviewers and gives them 2 working days to respond. If they are not available within the timeline, the Chair assigns other reviewers.

6.5.3. Provision of documents and evaluation forms to reviewers:

The Administrative Secretary prepares the pertinent documents (for initial submissions- the complete protocol and related documents; for post approval submissions- the protocol and the post-approval report), transmittal letter, protocol and ICF assessment forms for delivery, either through manual delivery or through electronic mail, to the assigned reviewers.

6.5.4. Accomplishment and Submission of evaluation forms:

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The reviewers review the study protocol and informed consent documents in accordance with the assessment points and elements detailed in UPCHE REC Form 8 [Study Protocol Assessment Form] for the scientist member and UPCHE REC Form 9 [Informed Consent Assessment Form] for the non-scientist member.

The reviewers accomplish the forms with appropriate comments and recommendations and return them to the Administrative Secretary within 10 working days from receipt of package.

6.5.5. Finalization of the review results:

The Chair consolidates the comments and decisions of the primary reviewers. If the reviewers have considerably different opinions about the study, the Chair may give the final decision or s/he may refer it for full review. Expedited study protocols that are disapproved by any primary reviewer are referred for full review.

Decision points for expedited review are:


- Approval
- Minor Modification
- Major Modification
- Disapproval

The criteria for Major and Minor Modifications are as follows:

- a. Major Modification - recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research; examples: major revisions in protocol design or method or ICF, inclusion/exclusion criteria, safety issues, data privacy issues
- b. Minor modification – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g. incomplete documentation, informed consent elements, unsatisfactory informed consent format), administrative corrections like typographical or grammar errors, minor changes on items not related to the procedure to be done

6.5.6. Communication of the REC decision to the PI:

- a. After the expedited review, the Secretariat prepares the protocol review decision – related documents, and the Chair signs and endorses the same to the Administrative Secretary.

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- b. The Administrative Secretary notifies the PI of the protocol review decision earliest within three (3) working days after receipt of decision by the Primary Reviewers. Notification may be accomplished via hand-carried mail, courier service, or e-mail.

6.5.7. Filing of documents in the protocol file folder and updating the protocol database:

A copy of the protocol and related documents are filed in the protocol files under Active Files (see SOP 21 Communicating REC Decisions; SOP 23: Management of Active Files). The Administrative Secretary updates the protocol database with the result of the REC action on the expedited reviewed protocol.

6.5.8. Inclusion of the Review Report in the Agenda of the next REC regular meeting:

The Secretariat includes the expedited reviewed protocol in the agenda for the next REC meeting (see SOP 18 Preparation of Meeting Agenda).


7. 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 15: Transmittal Letter
- Form 16: Action Letter - Approval of Protocol
- Form 17: Action Letter - Modification of Protocol

8. 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 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 Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	Policy: Added mechanism for appeals: The proponent/s may appeal any decision of the REC by submitting a letter containing the justification for the appeal addressed to the Chair. All appeals will be discussed in a regular committee meeting. Scope:

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			<p>Changed the scope of the SOP to begin with the accomplishment and submission of the evaluation forms by the Primary Reviewers. The initial Scope started with the assignment of reviewers or independent consultants. This step has been incorporated in SOP 4: Management of Initial Submissions.</p> <p>Responsibilities: Removed the responsibility of the Chair to decide whether the study protocol is for full board review, expedited review or exempted from review. The responsibility is now shared by the Chair, REC discipline expert, and non-affiliate member. This was added to SOP 4 under Responsibilities section.</p> <p>Workflow: The first 2 steps were incorporated in SOP 4: Management of Initial Submissions. The workflow now starts with the accomplishment of the assessment forms. The number of days for each step was changed to ensure that REC members have ample time to review the protocols. For example, the original time frame specified as '3 working days' was changed to 'earliest within 3 working days.'</p> <p>References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section.</p>
	21 September 2022	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	Revised the SOP right header box to include a simplified SOP code and added date of approval Policy: Revised statement regarding appeals for disapproved protocols to "For disapproved protocols, the proponent/s may appeal to the REC by submitting a letter containing the justification for the appeal addressed to the Chair (see SOP 27 Management of Appeals)."
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.	Added timeline (in working days) for each step in the Workflow

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		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)
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. Corrected the number of working days in 6.5.4. Accomplishment and Submission of evaluation forms from 5-7 to 5-10 working days.