

 ATENEDE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 4.3
	4.3 Full Review	Version No: 03
		Approval Date: 08/01/16
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1. Policy Statement

The UREC generally conducts two types of review: expedited or full review (refer to SOP 4.2 on Expedited Review). The Chair makes the final determination of the type of review the protocol will undergo, prior to assignment to reviewers. Although the application form instructs the proponent to categorize his or her protocol, this is mainly to facilitate documentation by the Secretariat and for the proponent to exercise self-reflection of the risk level of his or her protocol.

In the full review process, two UREC reviewers are assigned to conduct the initial review, after which these initial recommendations and the full protocol submission are discussed and deliberated in a convened UREC plenary meeting where a quorum of members is present.

1.1 Criteria for full review

The protocol is subject to full review in a convened UREC plenary meeting if:

- the risk level of the study is greater than the probability and magnitude of physical and psychological harm that is normally encountered in daily life; or in the performance of routine medical, dental, or psychological examination of healthy persons (i.e. “greater than minimal risk”); and/or
- the study procedures cannot be categorized among the types of studies eligible for expedited review

The involvement of vulnerable groups (e.g. children, prisoners, indigenous groups) as participants in the study may also necessitate full review.

1.2 Ethical basis for recommendations and decision-making in a full review

The UREC bases its recommendations and decisions on national and international standards for ethics in research involving human participants. Mainly, the AdMUREC standards are based on the 2011 National Ethical Guidelines for Health Research, the 2011 WHO Standards and Operational Guidance for Ethics Review, applicable provisions of the U.S. Federal Policy for the Protection of Human Subjects or the “Common Rule” (note that the AdMU has Federalwide Assurance from the U.S. Dept of Health and Human Services Office for Human Research Protections), and the 1979 Belmont Report.

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UREC recommendations and decision-making involve the following key considerations (refer to the Protocol Assessment Form for more details):

- Scientific design and conduct of the study [scientific justification and soundness of methods; qualifications of research personnel; adequacy of resources]
- Risks and potential benefits [minimization of and measures to mitigate potential harms; balance of potential benefits of the research vis-à-vis the risks; probable adverse events and protocols to address]
- Selection of study population and recruitment of research participants [justification of sample characteristics; fair and equitable distribution of potential benefits and potential risks of participation in the selection of participants]
- Inducements, financial benefits, and financial costs [just reimbursement or compensation of costs to participation, without undue coercion or influence]
- Protection of research participants’ privacy and confidentiality
- Informed consent process [assurance of voluntary consent with full information about the research; appropriate consent considerations and measures for persons unable to provide informed consent]
- Community considerations [community participation; respect for community traditions; community benefits vis-à-vis harms]

2. Objective/s and Scope of the Activities in SOP 4.3

The guidelines and procedures indicated in this section ensure that the evaluation of studies that require full review (i.e. entail greater than minimal risk to study participants, and/or involve participants in a vulnerable group), demonstrates due diligence and compliance with national and international standards in the protection of human participants.

2.1 This SOP applies to initial and post-approval (i.e. continuing review; protocol amendment) protocol submissions which have been classified for full review.

2.2 This SOP may apply to independently-conducted student research projects such as theses, dissertations, honors/capstone/ internship projects and the like if they necessitate full review (also refer to SOP 4.4 on Review of Class-Based Student Research). Student applications include a signed endorsement and acceptance of overall responsibility by a faculty supervisor.

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2.2.1 If the independent student research project undergoes a technical review process (e.g. a formal departmental defense) then the application for ethics clearance takes place after the defense to help ensure that the research is technically sound and that the protocol under ethics review would not still be undergoing significant changes.

2.2.2 The student and faculty supervisor should be mindful of the time period generally necessary for UREC review (for expedited, 2-4 weeks from submission; for full review, 4-6 weeks from submission) and schedule their research activities accordingly.

3. Workflow of Full Review Process and Persons Responsible

WORKFLOW OF FULL REVIEW (refer to SOP 2 for preliminary steps)	RESPONSIBILITY	WORKING DAYS
Step 1: Send ethics clearance application and protocol package to the assigned initial reviewers together with Protocol Assessment Form (PAF) <ul style="list-style-type: none"> • application may be for initial review, continuing approval, or protocol amendment 	UREO OA	(within 13 working days from receipt of complete protocol; see SOP 2)
Step 2: Include the protocol submission in the agenda of the next UREC plenary meeting (see SOP 5.1 on Preparing for a Meeting) and provide application and protocol package to all committee members	UREO OA	10-15 days prior to meeting date
Step 3: UREC deliberates on the protocol at plenary meeting, where initial reviewers present their PAF and recommendations (see SOP 5.2 on Conduct of Meeting)	UREC Members UREC initial reviewers	

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Step 4: Send UREC communication to PI (if approved, or minor/major modifications, or disapproved)	UREC Chair (<i>to approve and sign communications</i>) UREO Director (<i>to note and sign communications</i>) UREO OA (<i>to draft communications</i>)	up to 10 days from plenary meeting
Step 5: [If applicable] Respond to UREC recommendations for minor or major modifications and submit revised application	Principal Investigator	5-10 days from receipt of UREC notice
Step 6: Revert to Steps 1-4	UREO OA UREC initial reviewers UREC Members	communication sent to PI - up to 10 days from plenary meeting
Step 7: Document and file all submissions, recommendations, and decision for the protocol	UREO OA	

4. Description of Procedures

4.1 Send ethics clearance application and protocol package to the assigned primary reviewers together with Protocol Assessment Form (PAF)

At least two members are invited by the UREC Chair to serve as initial reviewers of the protocol (refer to SOP 2 on Management of Initial Submissions): one (1) of the reviewers must be in the same or allied discipline as the principal investigator, or have disciplinary familiarity with the topic of the research; the other reviewer is from a different discipline, for a balance of perspectives.

Once the assigned reviewers signify their agreement to review the protocol, the UREO OA sends the full protocol package and the Protocol Assessment Form to the reviewers. Unless the reviewers request a printed copy, a digital zipped file of the protocol submission is emailed to the reviewers. The zipped folder and files are appropriately labeled with the AdMUREC ID number (refer to SOP 2 on Management of Initial Submissions).

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4.2 Include the protocol submission in the agenda of the next UREC plenary meeting (see SOP 5.1 on Preparing for a Meeting) and provide application and protocol package to all committee members

The UREO Secretariat includes the protocol submission in the agenda for the next UREC plenary meeting. The ethics clearance application and protocol package are sent via email or hand-delivered (if printed) to the UREC members. UREC plenary meetings with full-review protocols on the agenda must have a quorum of members in attendance (refer to SOP 5 on Meeting Procedures).

4.3 UREC deliberates on the protocol at plenary meeting, where initial reviewers present their protocol assessment and recommendations (see SOP 5.2 on Conduct of Meetings)

The initial reviewers evaluate the protocol and relevant materials (i.e. instruments, informed consent forms, etc.) and complete the PAF, prior to the scheduled plenary meeting.

The protocol submission is deliberated on at the meeting, with the UREC Chair facilitating the discussion. The initial reviewers present their evaluation (as summarized in the PAFs) and recommendations, and the rest of the committee is requested to give their inputs. The general flow of the presentation and discussion follows the Protocol Assessment Form:

- scientific design
- research personnel
- participant selection and recruitment
- risks and benefits
- privacy and confidentiality
- informed consent forms and process
- other issues

If an independent consultant was assigned to review or comment or clarify aspects of the protocol, the UREC Chair presents the consultant’s report and the committee considers this in their evaluation. There may be instances when the principal investigator is also invited to present or answer questions during the meeting. The principal investigator is invited inside the meeting venue only after the initial discussion on his or her protocol,

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upon the signal of the Chair, so as to better organize the questions and issues to be raised with him or her.

The UREC may recommend the following actions on the protocol: approve, disapprove, minor modifications, major modifications, or other action. The recommended modifications and other actions must proceed via consensus or general agreement of the whole body (i.e. all members present find the decision to be acceptable). Decisions on ethics approval or disapproval of the protocol (i.e. for final disposition) are arrived at via consensus, whenever possible. If consensus is not reached, a decision is made via a voting process (i.e. raising of hands), wherein the decision of the majority is passed. Only UREC members who are present during the deliberations on the protocol can vote. The UREC Secretariat and UREC Director do not vote.

4.4 Send UREC communication to PI (if approved, or minor/major modifications, or disapproved) (See SOP 6.2 Communicating UREC Decisions)

If the decision is to approve the protocol, an ethics clearance letter is sent to the Principal Investigator.

If there are recommended major or minor modifications, or further action on the part of the Principal Investigator, the notification letter with consolidated reviewer recommendations, comments, and questions is sent to the Principal Investigator.

If the protocol is disapproved after the UREC plenary deliberation, a notification of the UREC decision is sent to the PI with the justification for the disapproval.

In UREC communications for protocols that undergo full review, the draft letter is prepared by the UREC Member-Secretary based on the minutes of the plenary meeting (SOP 6.1 and 6.2); the UREC Chair reviews the draft letter and edits it if necessary. The UREC Chair signs it and the UREC Director notes and signs the letter.

The communication is sent to the PI no later than 10 working days after the plenary meeting when the protocol was discussed.

4.5 [If applicable] Respond to reviewers’ recommendations for minor or major modifications and submit revised application

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The PI is given 5-10 working days to respond to the recommendations (due date depends on the complexity of the modifications). The resubmission of modified documents and the response to questions and comments is sent to the UREO OA.

If the PI is unable to submit his/her response within 10 working days, the UREO OA will request a letter from the PI that explains the failure to submit a response and may request an extension. This letter must be signed by the adviser (if applicable). If the PI does not submit this letter within 10 working days, the protocol is considered to have been withdrawn and there will be no more forthcoming work on it.

Responses from the PI may be accepted only up to a maximum of two months after the notification letter is sent by the UREO OA to the PI. If the PI still wishes to pursue ethics clearance for his/her project after this period, he/she will have to resubmit the protocol; this will be considered a new submission. When possible, this resubmission will be assigned to the same two primary reviewers.

4.6 Revert to steps 1-4

The UREO OA receives the protocol resubmission and accompanying files, which are labeled and filed according to the protocol ID number. The resubmission is entered into the UREC database and is included in the agenda of the next plenary UREC meeting.

The UREC Chair sends the revised and resubmitted application to the UREC initial reviewers is included in the agenda of the next plenary UREC meeting.

The initial reviewers evaluate the resubmitted protocol, revised attachments, etc., and present their recommendations at the next plenary meeting (refer to steps 3 and 4 of workflow).

If further modifications are recommended, or if the protocol is approved, the appropriate communication is sent to the PI.

4.7 Record and file all submissions, recommendations, and decision for the protocol

When a final disposition on the protocol has been issued, the UREO OA records this in the database and files all pertinent documents for the protocol in digital copies of folders. (Refer to SOP 7.1 on Managing Files.)

5. Forms and Templates

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AdMUREC Form 1 - Application Form for Initial Ethics Clearance: Expedited or Full Review

AdMUREC Form 3 - Protocol Assessment Form

Template of letter requesting minor / major modifications

Template of ethics approval letter

Informed Consent Form Template

6. History of the SOP

Version No.	Date	Authors	Main Change
01	2017 Jan 30	Liane P Alampay (LPA)	
02	2017 May 26	LPA	In accord with PHREB recommendations: <ul style="list-style-type: none"> ▪ Inclusion of statement that the Chair makes final determination on type of review the protocol will undergo (p.1)
03	2022 May 11	Ronald Allan L. Cruz, Nico A. Canoy, Eduardo Valdez, Joseph Johnson, Alfred Pawlik	A section has been added that requires proponents who are unable to respond to reviewers' comments to explain their failure to respond and sets a maximum of two months to respond, after which any submission from the proponent on the same protocol will be considered a new submission.

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			<p>All references to hard copy submissions have been removed; hard copies of documents are no longer required for submission.</p>
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