 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
	3.1 Review of Post-Approval Applications: Continuing Ethics Approval and Protocol Amendments	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

1. Policy Statement

Research ethics clearance is granted for a period of one (1) year in typical cases. The UREC requires the submission of a Continuing Ethics Approval application if the study has not been completed (i.e. if there are ongoing or future interactions with human participants) within the period of the initial ethics clearance. An application for Continuing Ethics Approval is submitted by the Principal Investigator no later than 45 days prior to the expiration of the initial ethics clearance.

The UREC likewise reviews and approves amendments to a previously approved protocol. The Principal Investigator submits an application for approval of amendments to the protocol together with the relevant amended documents (e.g. Informed Consent Form, instruments). The UREC must approve these amendments prior to the implementation of these changes in the study.


The Principal Investigator submits both the Continuing Ethics Approval application and the Protocol Amendment application if the continuing review also entails changes to the previously submitted and approved protocol. If there are no amendments, but an extension of the approval period is requested, then the Continuing Ethics Approval suffices; conversely, if the protocol is still within the time period of approval, but has revisions or changes, then the Protocol Amendment application is submitted.

1.1 Ethical basis for reviewing Continuing Approval and Protocol Amendment applications

In general, the ethical basis for reviewing post-approval applications is the same as in the initial review (see SOP 4.2 Expedited Review, SOP 4.3 Full Review).

For continuing approval applications, most pertinent to consider is whether new information has emerged since the initial ethics approval that could alter the UREC's previous determinations with respect to risk to participants. Information regarding unanticipated problems and adverse events that have occurred since the previous review will also be important to consider. The UREC also determines whether any provisions for monitoring the study under the previously approved protocol have been implemented and are working as intended.

2. Objectives and Scope of the Activities in SOP 3.1


 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
	3.1 Review of Post-Approval Applications: Continuing Ethics Approval and Protocol Amendments	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

The procedures indicated in this SOP ensure that research studies which require post-approval review, i.e. continue beyond the initial ethics approval period, and/or which have proposed amendments or revisions in design, sampling, methods, etc., continue to be evaluated and checked for compliance with national and international ethical standards.

The procedures in this section apply to protocols where data collection or interactions with participants extend beyond the one-year period of ethics approval (or the period indicated in the ethics approval letter, if not one year). They also apply for applications to review changes or amendments to the initial approved protocol.

3. Workflow of Review of Post-Approval Applications and Persons Responsible

WORKFLOW OF REVIEW OF POST-APPROVAL APPLICATIONS	RESPONSIBILITY	WORKING DAYS
Step 1: Receive Application Form and protocol package from PI (one of the following:) <ul style="list-style-type: none"> ▪ Continuing Ethics Review ▪ Protocol Amendment Form 	UREO OA	
Step 2: Determine if the application and protocol package is complete; inform PI if incomplete	UREO OA	0-2 days from submission
Step 3: Record and code complete applications in UREO database of ethics clearance applications <ul style="list-style-type: none"> ▪ file is assigned <u>the same ID code as initial submission, but with appropriate suffix, e.g. "CR1" or "PA1"</u> 	UREO OA	0-3 days from complete application
Step 4: Forward application to the UREC Chair (cc UREO Director) <u>together with retrieved original protocol file and relevant past submissions</u>	UREO OA	
Step 5: Determine the type of review required	UREC Chair	0-5 days from receipt of application from UREO Secretariat
Step 6: Assign and forward the continuing / protocol amendment submission to the UREC	UREC Chair	

 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
	3.1 Review of Post-Approval Applications: Continuing Ethics Approval and Protocol Amendments	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16


WORKFLOW OF REVIEW OF POST-APPROVAL APPLICATIONS	RESPONSIBILITY	WORKING DAYS
members who had reviewed the initial submission, together with retrieved original protocol file and relevant past submissions <ul style="list-style-type: none"> UREC Chair may review and approve continuing approval submissions which do not involve changes or amendments to protocol since initial approval 		
Step 7: Indicate acceptance or non-acceptance of assignment	UREC Member	0-5 days from notice of assignment from UREO Secretariat
Step 8: Record assigned reviewers to protocol submission		up to 13 days from receipt of complete application
Step 9: Revert to Expedited Review Process or Full Review Process (refer to relevant SOP)	UREC Reviewers UREC Chair UREO OA	

4. Description of Procedures

4.1 Receive Application Form and protocol package from Principal Investigator

A complete protocol submission consists of digital PDF copies of all required materials, sent to the official email address of the UREO . The complete protocol package for a post-approval review includes:

- Application Form: Continuing Ethics Review and Clearance and / or Research Protocol Amendment Form
- If applicable, pertinent materials that have been changed or amended in the research protocol (e.g. detailed description of amendments in methods, such as sample, recruitment, instruments, procedures; revised instruments; revised informed consent forms)

 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
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4.2 Determine if the application and protocol package are complete

4.2.1 Using the “Ethics Clearance Application Checklist,” the UREO OA checks whether the submission is complete. The PI is informed by the OA of missing documents and/or items left unanswered in the application form within 2 working days from submission

4.2.2 When complete, the OA prepares the dated and signed acknowledgment receipt for the protocol package (part of the “Ethics Clearance Application Checklist”) and provides a copy to the Principal Investigator.

4.3 Record and code complete applications in UREO database of ethics clearance applications


4.3.1 The UREO Secretariat assigns the same ID number as the original submission to the post-approval application, but with the appropriate suffix. Thus, the ID corresponds to: a) the school year, b) serial number, c) protocol amendment or continuing review number. For example, the 17th application in the school year 2015-2016 is coded as AdMUREC_2015_017; the first protocol amendment (“PA”) is coded as AdMUREC_2015_017_PA1; the first continuing review (“CR”) submission is coded as AdMUREC_2015_017_CR1

4.3.2 File names of soft copies of documents and attachments pertaining to the protocol submission are also tagged with the same code.

4.3.3 All documents are placed in the same file or digital folder as the original protocol submission .

4.3.4 Aside from the digital file folders and the paper folders, protocol records are entered into a password-protected electronic database. The UREO OA also maintains a physical logbook where each protocol submission is recorded. Both digital and physical databases are updated and the digital data is backed-up on a daily basis.

4.4 Forward application to the UREC Chair and UREO Director together with the retrieved original approved protocol file and relevant past submissions

 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
	3.1 Review of Post-Approval Applications: Continuing Ethics Approval and Protocol Amendments	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

After recording the submission, the UREO OA forwards the protocol package to the UREC Chair. The original approved protocol and other relevant past submissions are retrieved and also forwarded to the Chair for reference.

4.5 Determine the type of review required

The UREC Chair classifies the continuing and/or protocol amendment submissions as either for expedited or full review. (Refer to SOP on Expedited Review and SOP on Full Review for criteria and succeeding steps in the review.)

In general, expedited review is conducted for protocol amendments that:


- do not involve changes in study populations
- do not involve the collection of (additional or new) private information that may place participants at risk if identities are revealed
- do not change approved use of anonymized or archived samples
- do not involve further recruitment of participants
- involve study protocols previously classified under expedited review
- are administrative in nature (such as changes in major study personnel)
- do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants

Full review may be required for amendments that do not fall under the aforementioned, to be deliberated and decided on at a UREC plenary meeting.

Applications for continuing ethics approval which do not involve any substantial changes or amendments to the protocol since the initial approval may be reviewed and approved by the UREC Chair.

4.6 Assign and forward the continuing / protocol amendment submission to the UREC members who had reviewed the initial submission, together with retrieved original protocol file and relevant past submissions

A standard invitation to review is sent by email to the prospective UREC reviewers. The UREC Chair first assigns the continuing / amendment protocol submission to the UREC reviewers who had evaluated the initial submission. This is to make the review process

 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
	3.1 Review of Post-Approval Applications: Continuing Ethics Approval and Protocol Amendments	Version No: 02
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more efficient, as these reviewers are already familiar with the study protocol. For expedited reviews, two (2) UREC members are considered; for full reviews, two (2) UREC members are likewise considered as initial reviewers (refer to SOP on Expedited Reviews and Full Reviews).

If one or both of the original reviewers are unavailable or indisposed, the UREC Chair considers the roster of UREC members and the database of ongoing protocol reviews to determine appropriate UREC reviewers for the protocol, and to balance the workload of reviewers.

The UREC Chair may also invite an independent consultant if the continuing / amended protocol requires technical or specific expertise that the roster of UREC members is unable to provide (refer to SOP on Appointing Independent Consultants).

4.7 Reviewers indicate to the UREC Chair their acceptance or non-acceptance of the assignment (within 5 working days of receipt of request)

Reviewers indicate via replying to the email invitation their acceptance or non-acceptance of the assignment to review the continuing review/amended protocol. Conditions for non-acceptance include conflict of interest, inability to perform function in due time due to illness, leaves, etc.

If a UREC member declines to review a submission, new invitations are forwarded to other regular or alternate UREC members.

4.8 UREC OA records final assigned reviewers to the protocol submission

The OA tracks the due date for their initial recommendations or review and sends a reminder to the reviewer two days prior to their deadline. (See SOP 4 on review procedures)

4.9 Revert to Expedited Review Process or Full Review Process (refer to relevant SOP)

5. Forms and Templates

AdMUREC Form 2 - Ethics Clearance Application Checklist

AdMUREC Form 5 - Research Protocol Amendment Form

 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.1
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AdMUREC Form 6 - Continuing Ethics Approval Application Form

Template of letter to UREC member requesting to review the protocol submission

Template of letter requesting major / minor modifications

Template of ethics approval letter

6. History of the SOP

Version No.	Date	Authors	Main Change
01	2017 Jan 30	Liane P Alampay (LPA)	
02	2022 May 11	Ronald Allan L. Cruz, Nico A. Canoy, Eduardo Valdez, Joseph Johnson, Alfred Pawlik	All references to hard copy submissions have been removed; hard copies of documents are no longer required for submission.