 ATENEDE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 2
	2 Management of Initial Submissions	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

1. Policy Statement

The University Research Ethics Office (UREO) receives applications for research ethics clearance or approval from faculty, students, and staff of the Ateneo de Manila University. The Secretariat is responsible for checking the completeness of the submission, filing it, and forwarding it to the UREC Chair for classification and assignment to initial reviewers.

1.1 The UREO accepts submissions of research protocols for ethics review that possess all the criteria presented in subsections 1.1.1 to 1.1.3:

1.1.1 Proponents and/or participants of the research are Ateneo de Manila University students or personnel, and/or the study is conducted under the auspices of the Ateneo de Manila University. This would include the following situations:

1.1.1.1 The primary proponent of the study is a faculty, student, or staff of the Ateneo de Manila University

1.1.1.2 If the study has several proponents, and the Ateneo co-investigator is not the primary proponent of the study, the protocol is reviewed by the Ateneo UREC if the primary proponent's institution does not have a functional REC, and/or the primary proponent's institution and/or the research sponsor or funder requires that the protocol be reviewed by the Ateneo co-investigator's institution

1.1.1.3 The study involves Ateneo students, faculty, and/or personnel as participants

1.1.1.4 The study is conducted under the auspices of the Ateneo de Manila University (i.e. it falls within Ateneo jurisdiction; Ateneo is identified by name in the study, etc.)

1.1.2 The study is *research*, defined as a systematic investigation wherein the proponent poses research questions or hypotheses, collects quantitative or qualitative data in an organized way, analyzes results, and derives conclusions that are intended to contribute to generalizable knowledge. "Generalizable" knowledge is that which contributes to a theoretical framework of an established body of knowledge; and/or is to be generalized to populations beyond the sample or site of data collection; and/or is intended

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to be replicated in other settings.

1.1.3 The research involves *human participants*. A *human participant* is defined as a living individual about whom an investigator obtains:

- data through intervention or interaction with the individual or
- identifiable private information or identifiable human material or specimens

1.2 Class or student activities involving human participants but which are assigned primarily for pedagogical purposes (i.e. to teach research methods or deepen understanding of concepts) are not reviewed by the UREC; *however*, the course instructor and students are still required to behave in an ethical manner towards participants (i.e. minimizing risk, ensuring informed and voluntary consent to participate, and protecting privacy), as regulated by Departmental protocols. (See SOP 4.1 Exclusions and Exemptions; and SOP 4.4 Review of Student Research.)

1.3 In regular semesters, the UREC sets a deadline for accepting applications for ethics clearance. This deadline is set at 3 weeks prior to Finals week and is announced to the University community via official memo. This is to provide the UREC sufficient time to review and process all applications received in that semester by the end of the semester. This also permits the UREC reviewers to attend to their teaching commitments as the semester becomes more hectic prior to the Final exams. Acceptance of applications resumes on the first day of UREC office work in the succeeding semester.

2. Objectives and Scope of Activities in SOP 2


The procedures outlined in this section ensure that applications for research ethics clearance are properly received, recorded, classified, and assigned to reviewers promptly and efficiently.

The procedures are applicable only to the types of research protocols described in the policy statement of this SOP.

3. Workflow of Management of Initial Submissions and Persons Responsible (refer to SOP 4.4 for management of applications for student research)

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WORKFLOW OF MANAGEMENT OF INITIAL SUBMISSIONS	RESPONSIBILITY	WORKING DAYS
Step 1: Receive application form and protocol package from PI / applicant (one of the following:) <ul style="list-style-type: none"> ▪ Application Form for Ethics Clearance (Expedited / Full Review) ▪ Validation of Exemption from Institutional Review 	UREO OA	
Step 2: Determine if the application and protocol package is complete; inform PI if incomplete	UREO OA	0-2 days from initial submission
Step 3: Record and code complete applications in UREO database of ethics clearance applications	UREO OA	0-3 days from complete application
Step 4: Forward application to the UREC Chair (cc UREO Director) or UREO Director (for validation of exempt status, see SOP 4.1)	UREO OA	
Step 5: Determine the type of review required for the protocol submission (i.e. exempt from institutional review; expedited or full) <ul style="list-style-type: none"> ▪ see SOP 4 for processes of exemption, expedited review, full review, review of student research 	UREC Chair	
Step 6: Identify the reviewers for the protocol submission	UREC Chair	
Step 7: Forward the protocol submission to the UREC members assigned to undertake the initial review (for full) or expedited review	UREC Chair UREO OA	0-5 days from receipt of application from UREO OA

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WORKFLOW OF MANAGEMENT OF INITIAL SUBMISSIONS	RESPONSIBILITY	WORKING DAYS
Step 8: Indicate acceptance or non-acceptance of assignment	UREC Member	0-5 days from notice of assignment from UREO Secretariat
Step 9: Record final assigned reviewers to protocol submission	UREO OA	up to 13 days from receipt of complete application

4. Description of Procedures

4.1 Receive Application Form for Ethics Clearance 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 includes:

- Application Form for Ethics Clearance for Research with Human Participants (expedited or full review) or Form for Validation of Exemption from Institutional Review or Request for Approval of Class-Based Research (refer to SOP 4.1, 4.2/4.3, 4.4)
- Research protocol (may not be applicable for class-based research, see SOP 4.4)
 - title
 - investigators and affiliations
 - research objectives
 - significance
 - essential literature review/conceptual framework
 - methods: description of sample, recruitment, inclusion criteria; all instruments and procedures
 - ethical considerations pertinent to the study
- Participant recruitment materials

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- Informed Consent Forms (ICF) and Assent Forms (if applicable)
- Funding/Grant/Sponsor letter or contract (if applicable); letters from relevant collaborating offices (e.g. study sites/institutions)
- Instruments or questionnaires
- Class syllabus (for class-based research)
- 1-2 page curriculum vitae of Principal Investigator(s)

4.2 Determine if the application and protocol package are complete

4.2.1 Using the Ethics Clearance Application Checklist, the UREO OA check 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 initial 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 (see also SOP 7.1 on Managing Protocol Files)

4.3.1 The UREO Secretariat assigns a unique ID number to the application, corresponding to: a) the school year, b) serial number. For example, the 17th application in the school year 2015-2016 is coded as AdMUREC_2015_017

4.3.2 For class-based research, the appropriate suffix is attached to the ID number, i.e. "CBS" (class-based student research) . Thus, the submission is coded as AdMUREC_2015_017_CBS

4.3.3 File names of soft copies of documents and attachments pertaining to the protocol submission are also tagged with the same code (e.g. informed consent forms are given the file name 2015_017_ICF; instruments are given the file name 2015_017_instruments)


4.3.4 All digital documents pertaining to a particular protocol submission are placed in a single digital folder .

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4.3.5 Aside from the digital file folders and the paper folders, protocol records are entered into a password-protected electronic database (i.e. an Excel data file). 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 in an encrypted external hard drive on a daily basis.

4.3.6 The UREC database of ethics clearance applications is composed of the following entries:

- ID number
- Protocol title
- Principal investigator / Applicant
- Department / Center
- Status of Principal investigator (i.e. faculty, graduate / undergraduate student, staff, etc.)
- Date submitted (complete)
- Type of submission (i.e. initial, class-based, continuing, amendment)
- Type of review (i.e. no review-exempt, expedited, full)
- Type of review classified by (i.e. UREC Chair, UREO Director, etc.)
- Date protocol was sent to reviewers (i.e. after acceptance of assignment)
- Names of reviewers
- Date initial review is due
- Dates of reviewers' meetings / written correspondences (with documentation)
- Reviewers' initial recommendation (i.e. major revision, minor revision, accept, reject, further action/information)
- Date decision is sent to Principal investigator (via letter)
- (if applicable) Date of response or resubmission of Principal investigator
- (if applicable) Dates of reviewers' meetings / written correspondences on response/resubmission
- (if applicable) Reviewers' recommendation on response/resubmission of PI (i.e. major revision, minor revision, accept, reject, further action/information)
- (if applicable) Date decision is sent to Principal investigator (on resubmission)
- Date of research ethics approval

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- Expiration date of research ethics approval
- Date progress report(s) is (are) due
- Date progress report(s) is (are) submitted
- Date final report is due
- Date final report is submitted
- (if applicable) Dates of monitoring checks or site visits
- (if applicable) Report on monitoring checks or site visits
- Status: Active, Terminated, Suspended, Completed, Archived/Inactive

4.4 Forward application to the UREC Chair and UREO Director (within 3 working days from receipt of complete application)

After recording the submission, the UREO OA forwards to the UREO Director those submissions wherein the principal investigator self-classified the protocol as exempt (i.e. applicant submitted the Form for Validation of Exemption).

For other submissions (i.e. Application for Ethics Clearance for Expedited/Full Review and Class-Based Research), the UREO OA forwards the protocol package to the UREC Chair (cc UREO Director).

4.5 Determine the type of review required

The UREC Chair initially classifies the protocol submissions as either for expedited or full review. Class-based and undergraduate research can only undergo expedited review. (Refer to SOP 4.2 on Expedited Review and SOP 4.3 on Full Review for criteria and succeeding steps in the review.)

If the UREC Chair determines that the protocol submission is exempt from institutional review, he or she forwards this to the UREO Director for validation of exemption. (Refer to SOP 4.1 on Exemptions from institutional ethics review.)

4.6 Identify the reviewers for the protocol submission

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.

For expedited reviews, two (2) UREC members are considered: one (1) of the reviewers

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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.

For class-based and student research, reviewers from the LS subpanel for student research are assigned by the UREC Chair to review the class-based / student protocol. The reviewers are from the same school or department as the class-based / student protocol, but should not have any conflict of interest with respect to the application.

For full reviews, two (2) UREC members are likewise considered as initial reviewers, who are to conduct the initial review and present their recommendations at the scheduled UREC plenary meeting wherein the protocol will be discussed and decided on by a quorum of UREC members.

For graduate student research categorized for full review, the initial reviewers may be from the LS Student Research Subpanel and the same department or school as the student applicant (provided there is no conflict of interest).


The UREC Chair may invite an independent consultant if the protocol requires technical or specific expertise that the roster of UREC members is unable to provide (refer to SOP 1.3 on Appointing Independent Consultants).

4.7 Forward the protocol submission to the UREC members assigned to undertake the initial review (for full) or expedited review

A standard invitation to review is sent by email to the prospective UREC reviewers. The protocol package is sent to the reviewers to provide them the opportunity to peruse it and have a quick assessment of any conflict of interest issues (which must be reported). They are given up to 5 working days to respond to the request.

4.8 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 particular protocol. Conditions for non-acceptance include conflict of interest, inability to perform function in due time due to illness, leaves, etc.

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

4.9 UREO OA records final assigned reviewers to the protocol submission

The UREO OA sends the Protocol Assessment Form to the reviewer upon acceptance of the assignment. 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)

5. Forms and Templates

AdMUREC Form 1 - Application Form for Initial Ethics Clearance

AdMUREC Form 2 - Ethics Clearance Application Checklist

AdMUREC Form 3 - Protocol Assessment Form

AdMUREC Form 4 - Validation of Exemption from Ethics Review

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

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.