



ATENEO DE MANILA UNIVERSITY
UNIVERSITY RESEARCH ETHICS OFFICE

**Guidelines on the Scope of Research Ethics Committee (AdMUREC) Review:
Inclusions (Types of Research and Proponents) and Exemptions from Review**

A. Activities Required to Undergo Ethics Review

There is a wide variety of scholarly work that is undertaken by students, faculty, and staff in the University. The AdMUREC reviews and monitors specific types of scholarly work, defined as follows:

1. The activity is *research*, defined as a systematic investigation wherein the proponent:
 - Poses research questions or hypotheses
 - Collects quantitative and/or qualitative data in a systematic way
 - Analyzes results and derives conclusions that are intended to: contribute to a particular domain or body of knowledge, and/or be generalized or applied to populations beyond the site of the data collection or sample studied, and/or is intended to be replicated in other settings (e.g. does not include data collection for purposes of institutional monitoring or evaluation)
2. The research involves *human participants*, defined as living individuals about whom an investigator obtains and/or utilizes:
 - Information through interaction or intervention with the individuals; or
 - Identifiable personal information¹ or identifiable human material or specimens

The proponent should submit AdMUREC Form 1: Initial Ethics Clearance Application and other required materials as indicated in the Form 1.

If the activity is not research and/or does not involve human participants as defined in this guideline, no further action is required from the principal investigator with respect to the University Research Ethics Office (UREO) and the AdMUREC. However, the activity may require regulation from other bodies in the University and the proponent is enjoined to comply with these relevant University policies.

Important: For specific guidelines on undergraduate student research and activities, refer to: 1) Guidelines on Faculty-Initiated Class Activities and 2) Guidelines for Undergraduate Theses

¹ Identifiers include: name, residence, email address, telephone/cellphone number, birthdate, social security numbers, gov-issued ID numbers, financial accounts/records, biometric data, IP / device serial numbers, full face photo and/or video

B. Research Proponents Required to Undergo Ethics Review

Proponents or investigators should submit their research to ethics review if the scholarly work activity is *research* as defined in this guideline, and the 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.

1. The primary or co-proponent/investigator of the study is a faculty, graduate student, or staff of the Ateneo de Manila University
 - If the study has several proponents and ethics approval had been obtained by the co-proponents' institutions (e.g. as with international or institutional collaborations), the protocol is still processed by the UREO to ensure that procedures are ethical and appropriate for the local setting. The initial processing is not a full review and may result in a validation of the initial ethics approval, but a full AdMUREC review may be recommended in certain cases. Contact the UREO for instructions in this case.
 - If the study has several proponents and ethics approval had been obtained by the co-proponents' institutions, the AdMUREC will still review the protocol if the research sponsor or funder requires ethics review and approval in all collaborating institutions.
2. The study is conducted under the auspices of the Ateneo de Manila University (i.e. AdMU is identified as a proponent or sponsor in the study, etc.)
3. Research that involves Ateneo students, faculty, and/or personnel as participants but is not conducted by any Ateneo-affiliated researchers should first seek the approval of the units where the study will be conducted. The units decide whether, in principle, they will permit the study to be conducted in their unit (i.e. if procedures are feasible and the topic is relevant to the unit). If the relevant units grant permission, the proponent should then undergo AdMUREC ethics review.

C. Research Involving Human Participants Eligible for Exemption From Ethics Review

Certain types of research may be exempted from research ethics review if:

- 1) the research activities are minimal risk²
- 2) the study meets one or more of the categories listed herein

² Minimal risk is defined as 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.

The University Research Ethics Office (UREO) determines whether a particular research study is exempt via a validation procedure (proponent should submit AdMUREC Form 4: Validation of Exemption from Review and expect a response within 10 working days).

Exempt Research Categories

Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Both the procedures involve normal education practices (e.g. use of tests or assessments of performance) and the objectives of the research involve normal educational practices.

Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, UNLESS:

- (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
- (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

In addition:

Application of this exemption category to research with children is limited to the use of educational tests or to observations of public behavior where the investigator does not participate in the activities being observed. It cannot be applied to projects involving surveys or interviews with children.

Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under Category 2 of this section, IF:

- (i) the human participants are elected or appointed public officials or candidates for public office; or
- (ii) the law requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available; or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Category 5: Research and demonstration projects that are conducted by or subject to the approval of national or local government department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) public benefit or service programs;

- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures;
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

In addition:

- The project is supported and authorized by a national or local government agency
- The program under study delivers a public benefit or service (e.g. financial or medical benefit; or social, supportive, or nutritional services)
- The research or demonstration project is conducted pursuant to specific statutory authority
- There is no statutory requirement that the project be reviewed by a research ethics board or committee
- The project does not involve significant physical invasions or intrusions upon the privacy of participants
- The funding agency concurs with the exemption from institutional ethics review

Category 6: Taste and food quality evaluation and consumer acceptance studies if:

- (i) wholesome foods without additives are consumed; or
- (ii) a food is consumed that contains a food ingredient at or below the level for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the relevant national regulatory agencies