



ATENEO DE MANILA UNIVERSITY
UNIVERSITY RESEARCH ETHICS OFFICE

GUIDANCE NOTE:

INCLUSIONS, EXCLUSIONS, AND EXEMPTIONS FROM INSTITUTIONAL ETHICS REVIEW

A. ACTIVITIES REQUIRED TO UNDERGO ETHICS REVIEW BY THE UNIVERSITY RESEARCH ETHICS COMMITTEE (ADMUREC)

There is a wide variety of scholarly work that is undertaken by students, faculty, and staff in the University. The AdMUREC and UREO (University Research Ethics Office) review and monitor specific types of research, defined as follows:

1. The activity 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, i.e. contributes to a particular domain or body of knowledge, and/or is generalized to a larger population beyond the site of the data collection or population studied, and/or is intended to be replicated in other settings
2. The research involves *human participants*, defined as a living individuals about whom an investigator obtains
 - information through interaction or intervention with the individual; or
 - identifiable private information or identifiable human material or specimens

If the activity is not research and/or does not involve human participants as defined in this Guidance Note, no further action is required from the principal investigator with respect to the University Research Ethics Office (UREO) and the University Research Ethics Committee (UREC). 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 student research and activities, refer to Guidance Note on Student Research and Other Course-Related Activities that Involve Interactions with Other Individuals.

B. RESEARCH INVOLVING HUMAN PARTICIPANTS ELIGIBLE FOR EXEMPTION FROM ETHICS REVIEW

The following types of research may be exempted from research ethics review if the study meets one or more of the following criteria. The University Research Ethics Office (UREO) determines whether a particular research study is exempt. If exempt, the investigator will be so notified by UREO.

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 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 subjects.
- The funding agency concurs with the exemption.

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 regulatory agencies of the Department of Agriculture and the Department of Health

If activity is research and involves human participants, and is possibly eligible for exemption, the proponent should submit AdMUREC Form 4 - Validation of Exemption from Ethics Review to the UREO for evaluation and validation of exemption status.