ATENEO DE MANILA UNIVERSITY
LOYOLA SCHOOLS

GUIDELINES FOR CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS

Introduction

The Guidelines for Conducting Research With Human Participants were drafted as part of the implementing guidelines of the University Code of Research Ethics. The Loyola Schools Ethics Committee studied relevant models and documents, particularly the 2006 DOST-PCHRD National Ethical Guidelines for Health Research, the 2009 Code of Ethics of the Psychological Association of the Philippines, pertinent materials from other Jesuit universities, and research ethics standards of other countries.

As these guidelines cannot completely address all possible emergent ethical concerns, members of the LS community are encouraged to study the guidelines and make suggestions for its continuous improvement. The LS Ethics Committee will regularly discuss such suggestions and adopt amendments to the guidelines as necessary.

1. Obtaining Institutional Ethics Review and Approval

A. To ensure that participants' rights are protected, institutional ethics review and approval is required for research with human participants conducted under the auspices of the Ateneo de Manila University Loyola Schools. Depending on the nature and level of risk of the study, the research may be considered for regular or full review by the Loyola Schools Research Ethics Committee.

B. Undergraduate and graduate student research involving human participants that is undertaken as part of curriculum requirements, and faculty and staff research involving human participants that is considered minimal risk, is subject to ethics review and approval under Departmental protocols.

    1. Research that is considered minimal risk is one where the probability and magnitude of anticipated harm or discomfort experienced by the participant are not greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations. Minimal risk studies must involve anonymous data.

    2. If the research is not governed by Departmental protocols and/or is considered medium or high-risk, then it is necessary for the research to undergo review at the level of the Loyola Schools. In general, studies that require information that will identify (name, contact information, or other confidential information) a study participant will need approval from the LS Research Ethics Committee.

C. Refer to the attachments for the Research Ethics Review Flowchart and the Application Form for Regular and Full Review.

2. Maintaining Confidentiality

A. It is the researchers' duty to safeguard any information divulged by participants. It is also their duty to ensure that this information is secured and is not placed in areas, spaces or computers easily accessible to other unqualified persons.

B. It is the researchers' duty to discuss the limitations of confidentiality to participants, may it be due to regulated laws, institutional rules, or professional or scientific relationship. Such limitations of confidentiality should be explicitly indicated in the informed consent or in a confidentiality agreement signed by the researcher and participant.

C. Before the actual collection of data, and as part of the informed consent, researchers should explain explicitly to the participants all anticipated uses of the data or specimens they will provide.

D. No information shall be released by any researcher without prior written consent of the participant or unless the same is in compliance with any judgment or order by a competent legal authority.

E. If information from participants are coursed through an electronic transmission, it is the researchers' duty to inform the participants of risks to privacy.

3. Informed Consent to Participate in Research

A. Obtaining informed consent from research participants is required in Section IV.C of the University Code of Research Ethics. In obtaining informed consent, researchers shall inform participants about:

1. the purpose of the research, expected duration, and procedures;
2. their right to decline to participate and to withdraw from the research once participation has begun;
3. how to withdraw consent, if desired;
4. the foreseeable consequences of declining or withdrawing;
5. reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects;
6. any prospective research benefits;
7. protections and limits of confidentiality and/or anonymity;
8. incentives for participation; and
9. whom to contact for questions about the research and research participants' rights.

Researchers provide opportunity for the prospective participants to ask questions and receive answers.

B. Researchers conducting intervention research involving the use of experimental treatments must clarify to participants at the outset of the research:

1. the experimental nature of the treatment;
2. the services that will or will not be available to the control group(s) if appropriate;
3. the means by which assignment to treatment and control groups will be made;
4. available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun; and
5. compensation for or monetary costs of participating including, if appropriate, whether reimbursement from the participant or a third-party payor will be sought.

Additional considerations may be raised for the conduct of clinical trials.

C. Researchers should appropriately document written or oral consent, permission, and assent of participants. In cases when the research is exempt from obtaining consent from participants, the researcher must justify this exemption.

D. Researchers ensure that the consent form is translated in language or dialect that the participants

understand. Researchers shall take reasonable measures to guarantee that the information was understood.

E. For persons who are legally incapable of giving informed consent, researchers shall nevertheless (a) provide an appropriate explanation, (b) seek the individual's assent, (c) consider such persons' preferences and best interests, and (d) obtain appropriate permission from a legally authorized person, if such substitute consent is permitted or required by law. When consent by a legally authorized person is not permitted or required by law, we shall take reasonable steps to protect the individual's rights and welfare.

    1. When conducting research with persons below 18 years of age, informed assent is obtained from them and informed consent from their parents or legal guardian.

    2. When conducting research with adult participants who have difficulties in comprehension or communication, informed consent is obtained from the legal guardian or the person who has care and custody over the person.

    3. When research is conducted with detained or institutionalized persons, researchers must pay attention to special circumstances which could affect the latter's ability to give informed consent.

F. In longitudinal research where data is collected from participants at certain intervals of time, informed consent should be obtained at every occasion of data collection unless the intervals are very brief such that it is unlikely that the participants would reconsider their consent to participate.

4. Informed Consent for Recording Voices and Images in Research

No recording or other form of exploitation of voices or images or likeness shall be made unless full and informed consent in obtained; provided also that this is not against any law, rule, or regulation.

Obtaining full and informed consent for recording of voices or images is not required if:

1. The research consists solely of naturalistic observations in public places, and the recording will not be used in a manner that could cause personal identification or harm, or

2. The research design entails deception (see Section 8), and consent for the use of the recording is obtained during debriefing.

5. Dispensing With Informed Consent for Research

Researchers may dispense with informed consent in the following conditions:

1. Where research would not reasonably be assumed to create distress or harm and involves:

    a) the study of normal educational practices, curricula, or classroom management methods conducted in educational settings;

    b) only anonymous questionnaires, naturalistic observations, archival research, or use of biological specimens which cannot be linked back to the source, for which disclosure of information would not place participants at risk of criminal or civil liability or damage their financial standing, employability, or reputation, and confidentiality is protected; or

c) the study of factors related to job or organization effectiveness conducted in organizational settings for which there is no risk to participants' employability, and confidentiality is protected or

2. Where otherwise permitted by law or institutional regulations

When dispensing with informed consent, researchers shall nevertheless provide participants with an appropriate explanation of the study and inform them of their right to decline to participate and to withdraw from the research once participation has begun.

6. Client/Patient, Student, and Subordinate Research Participants

A. When researchers engage the participation of clients/patients, students, or subordinates, they must inform the participants of their right not to participate and take steps to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

B. When research participation is a course requirement or an opportunity for extra credit or other incentive, the prospective participant is given the choice of equitable alternative activities that could fulfill their educational, employment, or health goals.

7. Offering Inducements for Research Participation

A. Researchers should consider fair compensation of participants for the use of their time, energy, and knowledge.

B. Researchers should make reasonable efforts to avoid offering excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation.

C. When offering professional services as an inducement for participation, researchers clarify the nature of the services, as well as the risks, obligations, and limitations. (Additional considerations may be raised in conducting clinical trials, when the inducement for participation involves intervention or treatment of a medical, physical, or psychological condition.)

8. Deception in Research

A. Researchers do not conduct a study involving deception unless:

1. they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that

2. effective nondeceptive alternative procedures are not feasible and

3. there is no negative impact on the integrity and dignity of the human person

B. Researchers do not deceive participants or withold from them information about a study that is reasonably expected to cause physical pain or severe emotional distress. They do not deceive prospective participants about procedures and other aspects of a study that are expected to influence their decision to provide informed consent.

C. It is the duty of researchers to explain any deception that is an integral feature of the design and

conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

9. Debriefing

A. Researchers must provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the researchers are aware.

B. If scientific or humane values justify delaying or withholding information, researchers take reasonable measures to reduce the risk of harm.

C. When researchers become aware that procedures have harmed a participant, they take reasonable steps to correct or minimize the harm.

D. If, after debriefing, the participants decided to withdraw their data or specimens, the researchers shall respect and grant their request. The participants have the right to appeal that their own data, including recordings, be destroyed.