



Policy on Use of Human Participants in Research

"The decision to undertake research rests upon a considered judgment by the individual researcher about how to contribute to knowledge and human welfare. Having made the decision to conduct research, the investigator considers alternative directions in which research energies and resources might be invested. On the basis of this consideration, the researcher carries out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulations and professional standards governing the conduct of research with human participants."

From the *American Psychologist*, June 1981, 637-638

LaGrange College

Policy on Use of Human Participants in Research

The Institutional Review Board (IRB) is a committee that reviews all LaGrange College (LC) research involving human participants and is responsible to the President. The purpose of the IRB is to assure that research is conducted in an ethical manner. This includes ensuring that risks to participants are minimized, the selection of participants is equitable, and participants are informed fully of what their participation will entail.

This policy on the use of human participants in research applies to any activity deemed to be research at LaGrange College. The applicability of this policy is to all entities of the College: faculty, administration, staff, students, and contracted consultants. This policy applies to any research activity using human participants that is directly or indirectly supported by the College.

Background

The National Research Act of 1974, recognizing the need for safeguard regulations concerning the use of human participants in social and behavioral science research requires institutional review, letters of assurance, and documentation thereof for such research. The Federal Policy for the Protection of Human Participants, known as the Common Rule represents the latest Federal regulations for protection of human participants. This Policy went into effect June 23, 2005.

LaGrange College, like most institutions, shall review all research proposals involving human participants, whether funded or not. It is the policy of this College to apply the regulations to all research and research-related activities which involve human participants.

A copy of the current HHS regulations (45 CFR 46 Protection of Human Participants) pertaining to the use of human participants in research is available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102> or from the Office of the Vice-President for Academic Affairs and Dean.

Definition of Terms

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge [45 CFR 46.102]. Under federal regulations, research involving human participants is classified into three distinct categories or levels: exempt, expedited, and all other research. Exempt and expedited projects are considered no risk to minimal risk to human participants. All

other research is considered a potential risk to human participants or considered to place human participants at-risk. Any research involving minor children must have full board review.

Human participants are defined as living individuals about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (e.g., collection of human tissue, blood samples, pathology or diagnostic specimens) and manipulations of the participant or the participant's environment that are performed for research purposes. Much more common are *interactions*, which include communication or interpersonal contact between the investigator and the participant. *Private information* includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place. Thus, the individual will have provided the information for specific purposes and can reasonably expect that the information as associated with his or her identity will not be made public [45 CFR 46.102].

Minimal risk in research is defined as harm or discomfort of no greater probability and magnitude than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests [45 CFR 46.102].

General Ethical Guidelines for Research Involving Human Participants

- A. In planning a study, the investigator has the responsibility to make a careful evaluation of its ethical acceptability. To the extent that the weighing of scientific and human values suggests a compromise of any principle, the investigator incurs a correspondingly serious obligation to seek ethical advice and to observe stringent safeguards to protect the rights of human participants.
- B. Considering whether a participant in a planned study will be a "participant at risk", according to recognized standards, is of primary ethical concern to the investigator.
- C. The investigator always retains the responsibility for ensuring ethical practice in research. The investigator is also responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom, however, incur similar obligations.
- D. Except in minimal-risk research, the investigator establishes a clear and fair agreement with research participants, prior to their participation, that clarifies the obligations and responsibilities of each. The investigator has the obligation to honor all promises and commitments included in that agreement. The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explains all other aspects of the research about which the participants inquire. Failure to make full disclosure prior to obtaining informed consent requires additional safeguards to protect the welfare and dignity of the research participants. Research with children or with participants who have impairments that would limit understanding and/or communications requires special safeguarding procedures.
- E. Methodological requirements of a study may make the use of concealment or deception necessary. Before conducting such a study, the investigator has a special responsibility to:

1. determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value;
 2. determine whether alternative procedures are available that do not use concealment or deception;
 3. ensure that the participants are provided with sufficient explanation as soon as possible.
- F. The investigator respects the individual's freedom to decline to participate in or to withdraw from the research at any time. The obligations to protect this freedom require careful thought and consideration when the investigator is in a position of authority or influence over the participant. Such positions of authority include, but are not limited to, situations in which research participation is required as part of employment or in which the participant is a student, client, or employee of the investigator.
- G. The investigator protects the participant from physical and mental discomfort, harm, and danger that arise from research procedures. If risks of such consequences exist, the investigator informs the participant of that fact. Research procedures likely to cause serious or lasting harm to a participant are not used unless the failure to use these procedures might expose the participant to risk of greater harm, or unless the research has great potential benefit and fully informed and voluntary consent is obtained from each participant. The participant should be informed of procedures for contacting the investigator within a reasonable time period following participation should stress, potential harm, or related questions arise.
- H. After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen. Where scientific and human values justify delaying or withholding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.
- I. Where research procedures result in undesirable consequences for the individual participant, the investigator has the responsibility to detect and remove or correct these consequences, including long-term effects.
- J. Information obtained about a research participant during the course of an investigation is confidential unless otherwise agreed upon in advance. When the possibility exists that others may obtain access to such information, this possibility, together with the plans for protecting confidentiality, is explained to the participant as part of this procedure for obtaining informed consent.
- K. The IRB review process must be complete before data collection begins. The IRB will not review any project after the fact.

Types of IRB Review and Approval

Under the Federal Regulation [45 CFR 46], research involving the use of human participants is classified into three distinct categories or levels: exempt, expedited, and all other research. There are exclusive restrictions related to research involving participant populations that include prisoners, fetuses, pregnant women, children, institutionalized individuals (i.e., mentally disabled), other potentially vulnerable groups

and human in vitro fertilization. An outline of specific regulations relating to restricted research population can be obtained from the HHS regulations on file in the Office of the Vice-President for Academic Affairs and Dean.

LEVEL 1: EXEMPT RESEARCH

Federal regulations mandate that very narrowly defined types of research are exempt. Research activities in which the only involvement of human participants will be one or more of the following categories and which do not involve vulnerable populations are exempt from 45 CFR 46.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. Research on regular and special educational instructional strategies.
 - b. Research on the effectiveness of/or the comparison among instructional techniques, curricular, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants.
 - b. 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.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraphs 2.b of this section, if:
 - a. The human participants are elected or appointed public officials or candidates for public office.
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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.
5. Research and demonstration projects which are conducted by/or participant to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - a. Public benefit or service programs.
 - b. Procedures for obtaining benefits or services under those programs.
 - c. Possible changes in or alternatives to those programs or procedures.

- d. Possible changes in methods or levels of payment for benefits or services under those programs.
- 6. Taste and food quality evaluation and consumer acceptance studies,
 - a. If wholesome foods without additives are consumed.
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

LEVEL 2: EXPEDITED RESEARCH

Federal Regulation identifies ten restricted types of research which may be reviewed by the IRB using an expedited procedure. Research activities involving minimal risk and in which the only involvement of human participants will be in one or more of the following categories (carried out through standard methods) may be reviewed through the expedited review procedure authorized in 45 CFR 46.110.

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicated a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the participant or an invasion of the participant's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-ray, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from participants 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recording made for research purposes such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the

investigator does not manipulate participants' behavior and the research will not involve stress to participants.

10. Research on drugs or devices for which an investigational new drug exemption is not required.

LEVEL 3: ALL OTHER RESEARCH

All other research must be reviewed in full by the IRB.

Committee Composition

The LC IRB Committee is composed of seven members appointed by the Vice-President for Academic Affairs and Dean. The Chair is elected by the committee and (after the first year of committee operation) must be a person with a minimum of one year of service on the committee. Pursuant to the regulations [45 CFR 46.107], the committee shall consist of:

- a. individuals with varying backgrounds who are sufficiently qualified by experience and expertise to evaluate research proposals involving human participants.
- b. male and female representation.
- c. At least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- d. one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

A quorum will be satisfied at meetings in which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting [45 CFR 46.108].

IRB Application/Review Procedures

The IRB will meet at least four times a year (once a calendar quarter) as needed to review proposals, review progress reports, generate committee activity reports, or conduct business as deemed appropriate by the members of the committee. Minutes will be kept of all IRB meetings documenting actions taken, the vote on actions taken, a synopsis of discussions of controversial issues, the reasons for requiring alterations/disapproval in proposals, and members present at the meeting. All correspondence between the IRB and investigators shall be retained in the committee files which are located with the Chair of the IRB. All records shall be retained for at least three years. Records relating to research which is approved and conducted shall be retained for at least three years after completion of the research [45 CFR 46.115].

Application Process

Applications for IRB review shall be submitted to the committee through the Office of the Vice-President for Academic Affairs and Dean. All applications should include a completed IRB application form, a complete copy of the research proposal, and a copy of the informed consent and/or questionnaire to be used (if any).

1. **Exempt Application**

To apply for exemption from IRB review, the investigator must complete one copy of the IRB application form (see Appendix A), a copy of the research proposal, and attach a copy of the informed consent and/or the questionnaire to be used (if any). There are no deadlines for submission of an exempt application.

2. **Expedited Application**

To apply for expedited review, the investigator must complete one copy of the IRB application form (see Appendix A), a copy of the research proposal, and attach a copy of the informed consent and/or the questionnaire to be used (if any). There are no deadlines for submission of an expedited application.

3. **Full Review Application**

To apply for full review of all other research, the investigator must complete the IRB application form (see Appendix A – one original and seven copies), obtain any special approvals that may be required (one copy), attach the completed research proposal (eight copies), develop a consent form which is in compliance with IRB standards (eight copies), and any questionnaire to be used (eight copies). Eight separate packets must be collated and submitted two weeks prior to the scheduled committee meeting.

Review Procedures

Complete IRB applications will receive an initial evaluation by the chair of the IRB to determine content and impact of the project on human participants. The review process shall be executed as follows:

- a) **Exempt applications** shall be assigned for review by the chair of the IRB. These projects will be considered as they are received. Normally, exempt projects require five days.
- b) **Expedited applications** shall be assigned for review by the chair of the IRB. Expedited applications will be processed within five days (exclusive of weekends and holidays) of receipt by the sub-committee.
- c) **All other research applications** shall be reviewed/approved by the full IRB committee. Full review applications must be submitted at least two weeks prior to the scheduled meeting for consideration. In general terms, full review projects require between 2-4 weeks for review.
- d) **Risk Incident Report**

Investigators are responsible for immediate notification of the IRB in the event of any injury or psychological harm to a participant enrolled in a research activity at LaGrange College. The report (see Appendix B) should be completed and submitted to the chair of the IRB.

Continuing Review

Full board and expedited sub-committee review of projects involving human participants shall be reviewed annually by the IRB. Investigators are required to complete and submit a progress report requesting continuing IRB approval. All projects deemed to be exempt from review will not require a yearly review provided that there are no changes in research design or methodology.

Final Report

When the study is complete, the principal investigator will report to the IRB using the form in Appendix D.

Informed Consent

Informed consent is one of the primary requirements of research involving human participants. "*Informed consent*" is understood to mean that the researcher has obtained documented permission from the participant(s) to conduct the research, and that the participant(s) have full foreknowledge about the nature of the research, any benefits, the risks and procedures involved, and the potential side effects or repercussions involving his/her/their well-being, physical and personal integrity, and social standing. It is important to remember that informed consent is an ongoing process, not an event. An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence [45 CFR 46.116]. The investigator must retain the signed consent document for at least three years past the completion of the research activity in accordance with and to the extent required by 45 CFR 46.117. Examples of consent forms are located in Appendix D.

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