Lee University Institutional Review Board
Policies and Procedures – Updated Summer 2021

Code of Ethics for Research

All research at Lee University shall incorporate the integrity that would be expected from research conducted at a University where a personal commitment to Jesus Christ as Lord and Savior is the controlling perspective of the educational enterprise. Specific areas that require honesty and integrity include but are not limited to the following: developing steps to assure the accuracy of the results, using research tools and methods of analysis that are well suited to the research problem, interpreting results which are consistent with the data available, assigning the confidence level that the data warrants, and protecting the rights, privacy, and physical and mental welfare of all persons involved in human subject research. All findings and methods shall be honestly and accurately detailed in any resulting research reports.

The sacredness of human life as revealed in scripture is a predominant theme at Lee University. Therefore, human subject research shall follow the ethical principles and guidelines for protection of human subjects of research outlined in the Belmont Report as chronicled in the Federal Register (April 18, 1979). Lee University will also adhere to the Department of Health and Human Services policy on "Protection of Human Subjects" (Title 45 CFR, Part 46, revised January 15, 2009) in all research activities requiring human subjects. It is expected that all researchers will familiarize themselves with these policies and design their research accordingly. In addition, all research involving human subjects will be reviewed and monitored by an Institutional Research Review Committee in accordance with the above-mentioned policies.

In designing a study, the researcher at Lee University must assume the responsibility to evaluate its ethical acceptability. One fundamental principle to use as a guide in evaluation is respect for persons (subjects). Subjects should be treated as autonomous agents, and persons with diminished autonomy entitled to protection. Thus, the researcher should assess the risks and benefits of the study thoroughly. Another principle is beneficence. This implies not only respecting the decisions of the individual and protecting them from unnecessary risk, but making efforts to secure their well-being. The researcher is obligated to establish a clear and fair agreement with the research participants (informed consent) prior to their participation and then honor all promises and commitments in the agreement. Part of the informed consent agreement should include the method of reporting results and the plan for keeping records confidential.

A third fundamental ethical principle is justice. Justice in this sense involves the selection of subjects. Selection of the subjects should be monitored so that they are not chosen because of their easy availability, compromised position, or manipulability but for their relevance to the study. Justice also indicates that those subjects taking part in the study should benefit from the results of the study.

Upon completion of the investigation, the researcher should provide the participant with information concerning the nature of the study and attempt to remove any misconceptions that may have arisen in a debriefing session particularly if the methodology of the study requires concealment or deception. Also, if any undesirable consequences have occurred, the researcher

has the responsibility to detect and remove or correct these consequences. Research undertaken following these fundamental guidelines will not only add to the existing body of knowledge in a particular field, but honor the basic Christian principles upon which Lee University was founded.

Definition of "Research"
Human subject research is a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge concerning living individual(s) about whom an investigator, whether professional or student, conducting research obtains data through intervention or interaction with the individual(s) or identifiable private information. This does not include research involving the collection or study of existing data, documents, records, pathological specimens if these sources are publicly available or research on elected or appointed public officials or candidates for public office.

Functions and Responsibilities of the Institutional Review Board (IRB)
The IRB will:

1. Review and approve, require modifications in (to secure approval), or disapprove proposals for all research activities covered by this policy.

2. Require information given to subjects as part of informed consent to be in accordance with standard regulations. The IRB may require that additional information be given to subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

3. Require documentation of informed consent or may waive documentation.

4. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

6. Advise appropriate University officials of current federal regulations or proposed changes in federal regulations pertaining to the protection of human subjects, and advise on University policy development and regulation changes which will best ensure the safety and health of human investigative subjects.

IRB Committee Membership
The IRB shall consist of at least five members. The members of the board shall be sufficiently qualified through the experience, expertise, and diversity of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The members, other than ex officio members, shall be appointed by the Provost of the University. The

membership shall include at least one member from the graduate program; one member whose primary concerns are in scientific areas; one member whose primary concerns are in nonscientific areas; and one member who is not affiliated with the institution or who is not a part of the immediate family of a person who is affiliated with the institution

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. The faculty member whose research is being reviewed may attend the session in which their proposal is being reviewed. Students may also be nominated by faculty members to attend board meetings. These nominations should be submitted to the chairperson who will review the agenda and determine the feasibility of student attendance. Neither students, other expert individuals, faculty whose research is being reviewed, or ex officio members may vote with the IRB.

IRB Committee Meetings

The IRB will meet regularly throughout each semester and in the summer on an as-needed basis. Special meetings may be called by the Chairperson as deemed necessary for the performance of IRB responsibilities. Convened meetings may occur in person, via videoconferencing, or through other approved mechanisms.

A simple majority of the membership shall constitute a quorum. If quorum is lost, no motions or votes may be presented. Any committee member may call for a secret ballot vote. If a member must be absent, notice should be given to the Chairperson as soon as it is known. Minutes of all IRB meetings will be recorded by the Chairperson or a designated representative.

Members of the committee will discuss the status of each research proposal under review. Before approving research, the committee will determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable relative to the anticipated benefits, if any.
3. Subjects are selected equitably.
4. Informed consent will be obtained from each subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. Data collection will be monitored (where appropriate) to ensure the safety of participants.
7. The privacy of subjects and confidentiality of data are maintained.
8. The inclusion of safeguards to protect the rights and welfare of all subjects, particularly those who are vulnerable to coercion or undue influence.

Review Procedures

All researchers involving human subjects in their work must submit the Human Subjects Review Form to the Office of Undergraduate Research & Scholarship (OURS) for review by the Chairperson of the IRB. Upon submission of the Human Subjects Review Form, the Chairperson (or a representative he/she designates from the IRB) shall determine if the research qualifies for an exempt, expedited, or full review (described later). If the research qualifies for

exempt or expedited status, the Chairperson (or the representative) has the authority to approve the research without a full review by the committee. An IRB member who is an author of a proposal for review should recuse himself/herself from the review process.

After reviewing each proposal, the IRB may approve, require modifications in (to secure approval), or disapprove proposals. The Chairperson (or designated representative) will then notify the researcher of the status of the research within one week of the date of submission. The IRB Chairperson or representative will maintain records of all research proposals and make these records viewable to all members of the committee.

Researchers whose research has been approved by the IRB will be notified in writing. The notification date will serve as the effective date of initial approval. Researchers who receive notice to modify their proposals should do so in a timely manner and clearly demarcate all changes to the original proposal before submitting a modified Human Subjects Review form to the Chairperson via the OURS. Researchers who receive notice that their research has been disapproved by the IRB may request additional information from the Chairperson about this decision and be given an opportunity to respond to the decision in writing.

Required Documentation

All researchers must submit the following documentation directly to the IRB Chairperson via the OURS before a review can begin. Additional documentation may be requested by the Chairperson to facilitate the review.

1. Human Subjects Review Form. (Consult the OURS for the most updated copy.)
2. Informed Consent* (or a request for waiver of consent)
3. Research Proposal (only if the research requires full-board review)
4. Responsible Conduct of Research (e.g., CITI training) completion certificate

*Researchers must obtain informed consent from each human subject involved in the research or the subject's legally authorized representative (unless the researcher is directed otherwise). The information should be presented in language understandable to the subject or representative. To constitute informed consent, the following information should be provided to each subject:

1. A description of the project, including its purpose and procedures.
2. Any possible risks or discomfort that a subject may experience.
3. Proposed benefits of the research.
4. Compensation given as a result of participating in the research.
5. Notice of the confidentiality of participants' data.
6. Notice of voluntary participation and withdrawal.

Project Categories

Once it has been determined that an activity is considered "human subjects research," it will be reviewed under one of three categories: Category I is eligible for "exempt review," Category II is eligible for "expedited review," and Category III requires "full review". The review procedures for each of these are described below. Each researcher should make the initial determination regarding the appropriate category of review, although the Chairperson may require review

under another category. The researcher can always request a higher level of review than that required.

Following are the project categories along with examples of the types of projects included in each category:

Project Category I: Exempt Review

Projects deemed eligible for exempt review (using exempt categories found at 45CFR 46.101b) are reviewed and approved by the Chairperson. Research projects in this category must involve minimal risk to the subject and must satisfy one or more of the following criteria:

1. Research conducted in established or commonly accepted educational settings (including K-12), involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, 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 subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. PLEASE NOTE: An exemption cannot be used when children are involved for research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

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 paragraph B. 2. of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (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 subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects, which are conducted by or subject 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; or (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, or (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.

Project Category II: Expedited Review

This research generally does not require written documentation of informed consent by law, but oral consent is required for all research involving direct interaction with subjects. However, it is undoubtedly safer to obtain written consent for all projects when possible. All research in schools requires written permission from the school district. Examples include:

1. Recording of data from subjects 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 subject, or an invasion of the subject'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-rays, microwaves).

2. 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 subjects 18 years of age or older, and who are in good health and not pregnant.

3. Voice recordings made for research purposes, such as investigations of speech defects.

4. Moderate exercise by healthy volunteers.

5. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

6. 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 subjects' behavior, and the research will not involve stress to subjects.

7. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

8. 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.

9. Collection of both supra- and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic sealing of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques.

Project Category III: Full Review

For all research involving subjects who have been determined to be "at risk", written documentation of legally effective informed consent is required. Research on minors or subjects incompetent to give consent requires permission by a parent or legal guardian. Deception research will only be approved if it meets certain conditions (e.g., debriefing). Examples include:

1. Research which might put subjects at risk beyond what they may experience every day.

2. Research involving psychological or physiological intervention.

3. Non-curricular, interactive research in schools.

4. Research involving deception that might have adverse effects on subjects.

5. Interviews or surveys on sensitive topics.

6. Research on special populations, such as minors, prisoners, and the mentally disabled.

7. Research conducted outside the US regardless of the procedures involved.

Sponsored Research Contracts

Any research conducted by a Lee University faculty member and/or student that may receive funding from internal or external sources should submit a research proposal to the Chairperson via the OURS for review prior to collecting data for the project. Although not all funding agencies require IRB approval at the time a funding application is submitted, the researcher should submit a proposal to the IRB in the early stages of the application process. Submitted proposals that are deemed preliminary or incomplete may be given temporary approval to facilitate approval of the funding application (if needed). However, a completed research proposal, including all methods and measures, must be submitted and approved by the IRB prior to data collection.

Changes to Approved Research

Researchers may not initiate changes to research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects (e.g., through training programs, materials for investigators, specific directives included in approval letters to investigators). Researchers must report changes in research to the IRB before they are initiated by modifying the Human Subjects Review Form and demarcating any changes made. The Chairperson will then review the modified Human Subjects Review Form and communicate with the researchers and/or IRB committee about the status of the research.

Continuing Review of Approved Research

The date on which the IRB Chairperson or representative notifies researchers of their approved research will serve as the effective date of initial approval. Researchers should communicate with the OURS if the research has not concluded within one calendar year of its initial approval. The IRB will then review the research again via an updated Human Subjects Review Form, which should be submitted to the Chairperson via the OURS. The Chairperson will then document the approval period in the IRB meeting minutes or elsewhere in the IRB records, and communicate the IRB's determinations to the researchers.

Research from Another Institution

Research that is reviewed and approved by an IRB at another institution need not be reviewed again by the Lee University IRB (allowable by federal law). However, a copy of the proposed research, the form submitted and approved, and any other documentation that was necessary for approval must be submitted to the Chairperson of Lee University IRB to be kept on file for the length of the research (if the research involves subjects at Lee University or the surrounding community). This will be true for faculty or others completing research for their dissertation that requires the use of human subjects from the Lee University campus or surrounding community. After viewing the submitted material, the Chairperson or the designated representative from the IRB has full authority to require a second review by the Lee University IRB if they deem it necessary.

Unanticipated Problems, Noncompliance, and Termination

All researchers are responsible for promptly reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA any unanticipated problems involving risks to human subjects or others; serious or continuing noncompliance; and/or suspension or termination of IRB approval. Researchers encountering unanticipated problems involving human subjects should communicate in writing with the IRB Chairperson, summarizing the problem, the outcome, and any steps taken to prevent recurrence.

Issues of noncompliance with the IRB policies, procedures, and/or determinations will be discussed by the committee. Any member of the committee may document issues of serious or noncompliance by summarizing the problem, the outcome, and any steps taken to prevent recurrence. The IRB reserves the right to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. If the IRB elects to suspend or terminate an approved study, the Chairperson will notify the researchers about the IRB's determinations in writing. The researchers will then inform subjects of the suspension or termination, and cease research operations until approval is returned (if applicable).