

FAQ

What is the purpose of the Lee College Institutional Review Board (IRB)?

The IRB is the Lee College committee that reviews and approves protocols for the use of human subjects in research. Federal regulations require that the IRB have at least five members representing a variety of backgrounds, training and experience, at least one member must have no formal or family connection with the System and be invited to serve as community representative. The IRB reviews research proposals to ensure that the rights and welfare of human subjects used in research studies are protected. The IRB assures that:

- Risks have been considered and minimized.
- Benefits have been identified and maximized.
- Subjects only volunteer to participate after being provided with legally effective informed consent.
- That all research is conducted in an ethical manner and in compliance with established standards.
- That all private information is handled with confidentiality.

How do I know if I am doing research?

Research is a systematic investigation including research development, testing and evaluations, designed to develop or contribute to generalizable knowledge. If you plan to present, publish, or otherwise share results of the study, it is generally considered research.

How do I know if I am using human subjects?

Human participants are defined as living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individual; or obtains data through identifiable private information. Some examples of human subjects/participants include:

- Individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities
- Oral history interviewees whose subjective perceptions are studied
- Students and teachers observed in the classroom for the study of various teaching methods or development of curricula

How do I know if I must submit my project for review?

If you are doing a study that involves people, then you should submit your project for review to the System Institutional Review Board. You might ask yourself, "Am I planning on:

- presenting the data of my project (using humans as test subjects) at an academic conference?
- publishing the data in an academic journal?
- using the research data in a master's thesis or doctoral dissertation?

If you answered **YES to any of the above**, your project is considered research and requires IRB review. If you answered **NO to all of the above**, your project is not considered research and will not require IRB review.

If your project is not hypothesis-driven, does not use research protocols and methodologies, and the anticipated data is not intended for publication or external release, no full IRB review is needed, *but* the protocol does need to be exempted by the IRB Office or the IRB Chair. If no public dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, you are advised to submit the project for IRB review and approval before research begins.

How do I submit my proposal?

Once you have determined that you are indeed doing human subject research you must fill out an IRB Research Application Form and submit an electronic copy with Informed Consent documents attached to the IRB office at IRB@lee.edu. Once the application is submitted, the IRB will make a determination on the status of the project, which will be Approved, Conditionally Approved, Tabled or Not Approved. No research may be conducted prior to receiving approval from the IRB. Any unapproved or conditionally approved research proposals will be presented in writing to the investigator along with any recommendations or suggestions.

How is my proposal reviewed?

Research proposals under review are categorized as follows:

Exempt

Some proposals fall into one of the "Exempt" categories as provided in federal regulations and as determined by the IRB, and does not require full IRB review. These proposals require IRB notification, but do not necessarily require review by the full convened committee. **Note:** Only the IRB Chair or IRB Office can determine Exempt status. In general, certain types of research are considered exempt:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices
- Research involving the use of educational tests, surveys procedures, etc., unless information is identifiable and disclosure would place subjects at risk. (Survey and interview research with children under the age of 18 are never exempt)
- Research involving the collection or study of existing data if the sources are publicly available or the information is recorded in a way in which the subjects cannot be identified
- Research and demonstration programs designed to study, evaluate or examine federal public benefit or service programs

Expedited

An expedited review consists of a review by the IRB Chair or designee. Proposals that satisfy the regulations may be given an expedited review, as determined by the IRB

Chair. The results will be communicated to the investigator in writing and also reported at the next IRB meeting. IRB members may ask for discussion of any expedited reviews.

Referred for IRB review

Proposals that are neither exempt nor expedited are sent to the full IRB for review.

Full Review

Proposals that involve more than minimal risk must go through full IRB review.

What is informed consent?

Informed consent is generally thought of as informing participants of the risks, benefits and methods of the research they are participating in. Informed consent means insuring that potential subject and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

Does research conducted as an Lee College employee require review?

If an Lee College faculty member or employee is investigating how to improve educational practice at Lee College, then it is generally not considered “research” as this IRB defines it. However, if research is done NOT as a part of that educator’s work at Lee College, is funded from an external funding source, research is for dissertation or thesis, or otherwise is not part of their work at Lee College, then that project would need to be reviewed.

Do classroom projects require IRB review?

Certain activities have the characteristics of research but do not meet the regulatory definition of research needing IRB review. For example:

- Data collected for internal departmental, school, or other administrative purposes (e.g. teaching evaluations, course evaluations)
- Research is a class project or term paper and will not be published in any form at any time
- Reviews and searches of existing literature and research involving a living individual, such as a biography, that is not generalizable beyond that individual

If ALL of the following criteria are met then IRB review is NOT required on the classroom project.

- The project is limited to surveys, questionnaires, interviews, observations of public behavior directly related to topics being studied in an official college course
- The above surveys, etc. contain no sensitive personal questions or other personal information that could stigmatize and individual
- No identifying information is recorded to link a person with the data such that it could reasonably harm the individuals’ reputation, employability, financial standing, or place them at risk for criminal or civil liability
- The participants in the project are not from a vulnerable or special population

- The collected data does not leave the classroom setting, or if the project involves collecting data on an organization, agency or company, the data is shared only with that entity
- No Lee College employee or student receives financial compensated for collecting, organizing, analyzing or reporting the data

Your project will require IRB notification and formal IRB approval if you do not meet **ALL** of the above requirements.

Do student research projects require IRB review?

Undergraduate research is to be encouraged, and learning the IRB review process is an important part of a college education. All undergraduate research will be submitted to the IRB for review. Undergraduates are to be strongly discouraged from engaging in research that poses more than minimal risk to subjects, as they are unlikely to have received sufficient training to safely conduct such research. Faculty members can encourage course research activities such that students become familiar with developing research proposals that can fall into the exempt or expedited categories.

Do class activities need review?

Students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require IRB approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to complete a Research Application Form and submit it along with the project and any accompanying consent forms and/or questionnaires in order to obtain the guidance of the IRB.

Can students be principal investigators?

No. The sponsoring faculty member must serve as the Principal Investigator (PI) and submit the application to the IRB. The student should be identified as the Co-PI. A sponsoring faculty member is responsible for student research. Faculty will inform students of human subject guidelines and take measures to enforce compliance to those guidelines. It is the responsibility of the supervising instructor/faculty member to determine whether projects are subject to review. It is always best to err on the side of caution and seek consultation from the IRB Office if a question arises regarding human subject research and classroom activities.

Do research studies involving children require IRB review?

ALL research with children including adolescents must be reviewed by the IRB committee. Children are considered a vulnerable population. They are less able to give fully informed consent with respect to the research involved. Safeguard procedures and considerations are, therefore, required by the Federal regulations for the review of research involving children. In most cases, written consent from a parent or legal guardian must be obtained if the research involves children under the age of 18.

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