

Getting Started

Lee College encourages and supports the scholarly endeavors of students, faculty and staff of the System. Scholarly work and research often involves the use of human subjects. All research involving human subjects conducted at or sponsored by Lee College, whether funded or unfunded and whether conducted by Lee College faculty or others, must comply with policies for the protection of human subjects and must be submitted for review to the appropriate review committee. Researchers may not solicit subject participation or begin data collection until they have obtained clearance from the IRB.

Lee College and federal policies require that projects involving human subjects be reviewed in order to consider:

- The rights and welfare of the subjects involved.
- The appropriateness of methods used to secure informed consent.
- The balance of risks and potential benefits of the investigation.

NOTE: It is expected that all research investigators will read all material on the IRB Web site and fully complete the application for IRB approval. The IRB will provide IRB members and research investigators with more information regarding the protection of human subjects upon request.

Submitting a Proposal

Please see the [Frequently Asked Questions](#) to get a general overview of the IRB responsibilities and general definitions.

Once you have determined that you are conducting human subject research there are a few easy steps to follow to complete the review process:

Step 1

Fill out the [IRB Research Application Form \(PDF\)](#) and submit via email along with any Consent Forms or additional documentation to be used for the project to IRB@lee.edu. (Be sure to save a copy for yourself.)

Step 2

Once the proposal is submitted the committee will review and make a determination as to the status of the proposal. The proposal will fall into one of four review categories:

Exempt

Some proposals fall into one of the “Exempt” categories as provided in federal regulations and as determined by the IRB. These proposals meet particular regulation and minimal risk requirements and may have an expedited review by the IRB Chair or designee. Exempt proposals do not mean exempt from review but exempt from a full committee vote, and possibly exempt from any continuing review based on length of the study. Only the IRB can determine Exempt status. The following types of research fall into the Exempt review category:

- 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 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 only by the IRB Chair or designee. Expedited reviews are for proposals that meet minimal risk standards as determined by the regulations and the Chair. Expedited reviews are normally faster than the full committee review and do not require a vote. 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, or the referral to a full committee review.

Referred for IRB Review

Proposals that do not meet Exempt review criteria, or proposals that the IRB Chair or designee cannot Expedite because they require further discussion are sent to the full IRB for review.

Full Review

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

Step 3

Once the category is determined the IRB or designees will review the Research Application Form and recommend one of the following:

- Approval: Proposal satisfies regulations and IRB requirements and research may commence
- Conditional Approval: Approval will be given once specific recommendations from the IRB are met. Recommendations will be given to investigator in writing, and no research may begin until revision have been evaluated
- Tabled: Not enough information provided on the Research Application to make an informed decision, additional discussion is required, or a majority of voting members could not be obtained
- Not Approved: Research proposal does not meet federal regulation or institutional requirements. Reasons for non-approval will be given to the investigator in writing.

Step 4

Once the committee has reviewed the Research Application Form, the Principal Investigator will be informed in writing, typically via email, of the status and recommendation. If approved, research may begin immediately upon receipt of the official correspondence.

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