

Information about the Institutional Review Board for UL Lafayette Graduate Students

Q: What is the IRB?

A: The Institutional Review Board is the University committee charged with the protection of the human individuals who participate in research and to protect the University from legal repercussions due to unethical research practices. Its mission is to protect research participants / subjects from harm.

Q: What needs I.R.B. review?

A: All theses, dissertations, capstone, DNP synthesis and research projects that have humans as research participants / subjects, or the data of living humans, no matter whether the research is carried out by students or faculty.

Q: When should my research project be reviewed?

A: According to Federal Regulations, any research plan involving human subjects must be reviewed and approved before any data are collected. While designing your study, you need to think about what you will do to the participants in your study. Then put yourself into the position of one of the participants: What protections, safeguards and guarantees would you want to see in place?

Q: Which categories of participants warrant special, careful scrutiny of a research application?

A: Some groups of potential participants are more vulnerable than others, and are specially protected: Persons who are incarcerated, hospitalized, or have limited ability to make decisions for themselves (such as young children, persons who are sedated, persons with mental or cognitive impairments, or anyone who has limited ability to consent). At UL Lafayette, our students are also included in the 'vulnerable' category, because students may feel pressured into taking part in research projects. The IRB also scrutinizes any pre-existing relationships between researchers and potential participants (for example, teacher-student, nurse-patient, therapist-client relationships) in order to safeguard that participants feel they have a genuine right to refuse to participate if they so wish.

IRB Contacts

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UL Lafayette IRB is on the web at:

vpresearch.louisiana.edu/research-compliance/institutional-review-board

Steps in the I.R.B. Review Process

Step 1: Research the ethical treatment of human subjects. Links to training sites can be found at:

vpresearch.louisiana.edu/research-compliance/institutional-review-board.

Another helpful site is

<http://www.dhhs.gov/ohrp/education/training/index.html>. The IRB General Guidelines for the University of Louisiana at Lafayette will guide you through the process of compiling your application.

Step 2: Complete Basic Human Subjects Research training course and get a certificate. All graduate students must complete the Basic Human Subjects Research training via the Collaborative Institutional Training Initiative. Instructions to register for the course are found at <https://vpresearch.louisiana.edu/research-integrity/institutional-review-board/citi-training>.

Step 3: Acquire all necessary forms: You can find the IRB application forms, guidelines, and other required parts of your application package (such as sample consent forms for participants) at <https://vpresearch.louisiana.edu/research-compliance/institutional-review-board/irb-forms>

Step 4: Complete the application form and assemble your application. The IRB application form is rather detailed, and it is very important that all questions are answered completely and clearly. You will also have to include consent forms for participants as appropriate, a research proposal that includes a description of the research methods to be used, and copies or descriptions of all tests, measures, or research instruments you intend to use in your study. Ensure that you explain clearly how you intend to protect your data after collection, how data are to be kept or destroyed after analysis, and how you intend to protect the identities and other personal details of your participants. We recommend that students planning a thesis or dissertation assemble their IRB application before their proposal defense and have their committee review it together with the proposal, so that only minor corrections are necessary before the proposal can be submitted for IRB review after the defense. On the application, you will indicate the applicable *level of review*. The level of review is chiefly determined by the risk to participants involved in the study. An exempt review is reviewed by one board member only. An expedited review is reviewed by two board members. A full board review is reviewed by a quorum of the full board. Review criteria and definitions can be found in the guidelines on the IRB website.

Step 5: Obtain advisor's confirmation of approval. When you have all the materials assembled get a letter from your research advisor stating that your proposal has been reviewed and approved, and attach that to the application. Some departments have a signature page marking the successful completion of the proposal defense.

Step 6: Carefully review your application. Use the checklist on the first page to determine if all the necessary parts are present. Every part of the application must be completed. This document is a legal record of your research protocols and should be sufficient so that a Federal Auditor would be able to see and know exactly what you were doing and that it had been approved. Applications with incomplete answers will be returned to your advisor for you to complete before the review process begins.

Step 7: Submit the completed application as email attachment. E-mail your completed application with all blanks completed to irb@louisiana.edu. Upon receipt, the IRB chair will assign a proposal number and reply with the status of your application. Please use this proposal number in all your communications regarding your application.

Step 8: Attend Institutional Review Board Meeting. If your proposal requires a full board review, you and your research advisor will be notified by e-mail of the date, time and venue of the review meeting. It is generally useful for both student and advisor to attend the meeting, in order to be able to answer questions that may arise during the discussion. The review committee will assist you in ensuring that your proposal conforms to the requirements and regulations for research involving human subjects (45-CFR-46, the Common Rule). After the discussion of your proposal, the committee will deliberate in private, after which you will be informed which corrections or modifications the IRB requires. Once the corrected material has been submitted and approved, you and your advisor will receive an approval memo.

Step 9: Renew approval as necessary and notify IRB upon project completion: Once you have submitted corrections and modifications to your proposal as required by the IRB, an approval memo will be sent to you and your advisor, and the paper copy of your proposal will be returned to your advisor. Exempt and expedited review levels for proposals do not require continuing review, unless the IRB deems it necessary. Annual continuing review is required for all applications reviewed via the full board **unless** data collection at all sites is complete AND data analysis is complete. If you are still analyzing or using data for any type of research write-up (e.g., dissertation paper, journal publication, etc.), the study must be re-approved by the IRB. When you have completed the project, please send the IRB chair a copy of the completion form (included with your approval memo) so that we may place your work into the completed files.

Good luck with your study!