GUIDELINES FOR APPLYING FOR APPROVAL OF RESEARCH INVOLVING HUMAN PARTICIPANTS

The following are instructions specifically tailored for student researchers, but may be helpful to any individual unfamiliar with obtaining Institutional Review Board (IRB) approval.

From the Policy Statement of the St. Lawrence University Institutional Review Board:

“In reviewing each proposal for projects involving human participants, the IRB shall determine whether these participants will be placed at risk and, if so, whether:

(a) The risks to the participant are so outweighed by the sum of the benefit to the participant or the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept these risks;
(b) The rights and welfare of any such participants will be adequately protected; and
(c) Legally effective informed consent will be obtained by adequate and appropriate means.
(d) The person(s) proposed to conduct the project are competent and qualified.”

1. General points
   • Submission of a proposal and approval by the IRB is not just a hoop your faculty advisor or course instructor is asking you to jump through. It is a legally mandated requirement for all research involving human participants conducted within the State of New York. Conducting research with human participants without prior IRB approval is not only in violation of St. Lawrence University policy, it is illegal.
   • Read the St. Lawrence University policy statement italicized at the top of this document. The policy statement guides the IRB when determining whether your study is ethical, so it should be one of your guides as well. All other requirements for approval from the IRB flow from the ideas contained within this policy statement.
   • Before you begin your application, read through ALL of the information on the IRB website (Informed Consent Checklist, Information for Faculty/Staff Directing Student Research Involving Human Participants, Proposal Checklist for Student Projects, and New York State Public Health Law [Article 24-A] and Ethics Statement) and familiarize yourself with the online proposal form and requirements. This information may affect the methodology of your study and will tell you what is required for approval by the IRB.
   • Note the deadlines for proposal submissions. These are firm. The IRB generally meets every two weeks during the semester, but not during University breaks, including the summer break.
   • While the IRB makes every effort to meet as scheduled, its composition at each meeting is specified by law. In the unusual instance that the IRB cannot be in compliance for a scheduled meeting, or simply has too many proposals to consider in one meeting, your Principal Investigator will be notified that review of your proposal will be delayed. This means you are best served by submitting your proposal in good time.
   • Accurate and thorough completion of this application will take you considerable time. However, spending time on it now will save you time later by increasing the likelihood that it will be approved. Incomplete or poorly prepared proposals will be returned without being considered.
   • Typographical errors, misspellings, incomplete or missing sections, and lack of specificity and clarity will all reduce the likelihood that your research will be approved. The IRB must be assured that the rights and welfare of participants will be protected in your study. If a proposal is sloppy, unclear and/or incomplete, the IRB will be unable to approve your study because it will not be assured of that protection.
   • If you have any questions or concerns as you are completing this application, feel free to contact the IRB Chair: Dr. Cathy Crosby-Currie, Department of Psychology, at x5167 or via email at cacrcu@stlawu.edu.

2. The application process
   • A proposal number will be assigned by the IRB when the IRB Chair receives your proposal. This number will then be used to track your proposal, and will appear on any correspondence you receive. If your
Every study requires that a faculty or staff member act as Principal Investigator (P.I.). Ask your faculty or staff advisor for the information regarding his/her title, department, phone number, and email address.

All collaborators/student researchers must be listed along with their contact information.

Consult the P.I. when you are choosing a title for the project. The title should be descriptive of the study but concise.

Make certain you complete in detail all the information required on the online proposal form and attach all supporting documents (Informed Consent statement, any questionnaires, surveys, interview schedules/guides, or other data collection instruments, etc.). See both Informed Consent Checklist and the Proposal Checklist for Student Projects for more information and guidance. All attachments must be in PDF and uploaded in one file, with each document carefully labeled with its title/filename. These titles/filenames must match those presented and discussed in the proposal document.

In the application process, you are required to list and discuss all potential risks to your participants. Do not write “no risks” without considering very carefully whether potential risks exist. Having potential risk for your participants does not mean your study is automatically unethical. If you do not consider the risks, do not take measures to minimize them, and do not demonstrate in your proposal the necessity for the risks and your steps to minimize them, your study will be considered unethical and will not be approved. The question of risk to participants must be given serious consideration. It is rare that there is absolutely no risk. The main point of the Informed Consent document is not to assure the participants that no risk is involved, but rather to describe that risk so that your participants may make a reasoned choice about their participation. You do not need to reassure the IRB that your research involves no risk, but rather that the risk is reasonable and is outweighed by important benefits, and that your participants are given enough information about the nature of the risk to choose whether or not to participate.

Everyone involved with the project must read New York State Public Health Law (Article 24-A) and Ethics Statement before submitting the proposal and check the box indicating that you have done so. This acknowledges that the Principal Investigator and all student researchers understand and accept ethical responsibility for the research in which you are involved.

3. Procedures after a proposal is submitted

Your proposal will usually be considered at the next scheduling meeting of the IRB, unless your materials arrive after the deadline for that meeting or the IRB receives too many proposals to be considered at one meeting. The Principal Investigator will be notified if the proposal will not be considered when expected.

The IRB members read each proposal prior to the meeting, make notes of any questions or concerns they might have, and then a quorum of the committee discusses each proposal at the meeting. After the discussion on a proposal is completed, a motion is made and seconded to either approve, approve with revision or table (not approve) the proposal. A vote on the motion is then taken, and if the majority agrees, that is the action taken. Most proposals are approved with revision because they contain minor omissions or errors that must be addressed before the research can begin.

After the meeting of the IRB, the Principal Investigator will receive an email and letter from the IRB Chair outlining the outcome of the IRB’s review. A copy of this letter is also sent to the student investigator(s) designated on the application form. If the proposal is approved, data collection can begin immediately. If the project is approved with revisions, the necessary revisions must be made and submitted to the IRB Chair who will review the revisions and, if accepted, inform the Principal Investigator that data collection can begin. If you begin data collection without submitting the revisions to the IRB Chair and receiving confirmation that it fulfills the IRB’s requirements, you are in violation of the law.

Once your proposal is approved, a Notification of Progress on or Completion of Human Participant Research form must be completed and returned to the IRB Chair by the Principal Investigator. If the human participant component of your project is not complete by 1 July of this academic year, the Principal Investigator on your project will need to apply to the IRB Chair for a continuation. A continuation request is usually approved, and is reviewed only by the Chair unless changes are being made affecting the use of human participants to the extent that a new proposal is necessary. Although
the Principal investigator is responsible for completing and submitting the completion/continuation form, the student researchers must make sure that the Principal Investigator is aware of the status of the project.