INFORMATION FOR FACULTY/STAFF DIRECTING STUDENT RESEARCH INVOLVING HUMAN PARTICIPANTS

The role of the Institutional Review Board (IRB) is to assess the potential for risk to participants and to insure that participants are fully informed about the research and risks so that they may voluntarily decide whether or not to participate. Both the Code of Federal Regulations (Title 45, Part 46) and New York State Public Health Law (Article 24-A) require all proposed research involving human participants be approved by the Institutional Review Board before it can proceed. Conducting research with human participants without prior IRB approval is not only a violation of St. Lawrence University policy, it is illegal.

Only faculty/staff of the university may serve as Principal Investigators (P.I.s) in research involving human participants. Students may not conduct such research without a faculty/staff P.I. who is the legally responsible party for the research. Although only faculty or staff of the University may serve as Principal Investigators of research involving human participants, we assume you want your students to have as close to a "Principal Investigator experience" as possible and, thus, have them craft the proposals for Institutional Review Board approval of their research. However, it is important for you to remember that you are the legally responsible party for the research, and the IRB assumes that the quality of the proposal and the mentoring/supervision of the research reflect your awareness of this. Based on our reading of many such proposals we offer a list of suggestions – by no means exhaustive – that we hope will help you and your students successfully navigate the review process. Please consider sharing these with your students. For more information, please also see Proposal Checklist for Student Projects, Guidelines for Applying for Approval of Research Involving Human Participants, and Informed Consent Checklist. Please also feel free to contact Dr. Cathy Crosby-Currie, IRB Chair, Department of Psychology, x5167, cacrcu@stlawu.edu.

1. Proposals are completed online and relevant attachments uploaded. Attachments must be combined in one PDF folder/file with each document clearly identified by a descriptive title/filename. Proposals must be complete and provide a detailed description of (a) the purpose of the research, (b) the methodology, and (c) risk to participants. The proposal must also include any required supporting documents (e.g., informed Consent documents) or appropriate attachments (e.g., questionnaires/surveys or interview schedules/guides). The IRB will not review any proposal that is incomplete.

2. The completed online proposal must be submitted electronically. Before doing so, please make certain you and your student(s) have read New State Public Health Law (Article 23-A) and Ethics Statement and checked the box acknowledging this.

3. The proposal should be clearly written, concise, well organized, and grammatically and syntactically correct. The IRB cannot consider any proposal found to be confusing or open to contradictory interpretations. The IRB membership must be able to clearly understand your intentions so that a proper assessment of risk to participants, how that is to be conveyed to participants, and how they are to make an informed decision about participation, can be determined upon review.

4. Anonymity and confidentiality are different conditions that apply to your research data collection methods. Promising anonymity means there will be no association of names with data. Promising to maintain confidentiality means the identifying information will be kept secret and private. For example, you cannot promise anonymity to someone you are going to interview face-to-face, but you can promise confidentiality. You cannot promise both anonymity and confidentiality. They are mutually exclusive conditions.

5. For most projects, the Informed Consent document is critical. For further guidance, see Proposal Checklist for Student Projects and Informed Consent Checklist. Solutions to some of the most common mistakes or omissions on this document are:
   a) Student names only may appear on the Informed Consent document. While student names may appear, the faculty/staff Principal Investigator(s) name(s), not the student name(s), must be provided both for
contact purposes and clarity about who is the primary, legally responsible, researcher for the project. The Informed Consent document must inform participants who to contact about any aspect of the project. Contact is always directed to the Principal Investigator(s). The Informed Consent document must contain information about how to contact the Principal Investigator(s) with telephone, mail, and email information provided.

b) If the project involves face-to-face interviewing the document must include a place for participants to sign. Participants take the document (or a copies of it), and you keep the signatures.

c) If recording is to be employed, you must obtain both the signature and, on the recording, an oral consent. A signature agreeing to be taped is in addition to the signature agreeing to participate in the research (thus, in this case, two signatures on the Informed Consent document are required). However, consent to record is not included as a separate document or as a separate section of the Informed Consent document; the two signatures are located in the same place on the Informed Consent document. You must also state that the recordings will be protected, where and how they will be securely stored, that they will be destroyed after transcription, and that pseudonyms will be employed in the transcriptions unless anonymity in the transcripts is not being promised.

d) In the case of surveys, an Informed Consent document must accompany the survey, but need not be returned with a signature. In this case, return of the survey constitutes implied consent.

e) The Informed Consent document must state the individual must be 18 years of age or older in order to participate

OR

If participants are members of vulnerable populations (minors, prisoners, etc.), you must provide a consent statement for the signature(s) of the guardian(s) or other legally authorized representative(s) of participants. Participants must then sign a statement of assent providing her/him with all the legally effective Informed Consent information about participation (including risks) so that the participant may assent to participation after their guardian or legally authorized representative consents to have her/him participate. In certain situations, a witness to the assent may sign. Because of the additional complexities of research involving vulnerable populations, you must be very clear about how you will obtain both informed Consent and assent and provide a rationale for your strategy.

f) The document should inform the potential participants that they may request that the Principal Investigator provide a summary of the research results once the project is completed and how this summary can be obtained. In some cases, this provision may be unnecessary or inappropriate. If you believe this provision to be unnecessary or inappropriate, provide your rationale for this exclusion in your proposal.

5. The question concerning the risk to the 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, weighing the risk and the benefits with enough information to make a decision about 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.

7. The IRB is a committee mandated by both Federal and New York State law. Your proposal is a legal document. All research is reviewed by the IRB for two reasons: (a) to help researchers be sure that they are protecting the participants in their research and (b) to protect the researchers from liability if something were to go wrong during the study. To do something in the way of research that is not documented in your approved proposal could be considered fraud and negate the protections afforded the Principal Investigator(s).

8. A proposal for research involving human participants requires a good deal of time, care, and thoughtful attention. Please do not assume your proposal will be approved simply because you submitted it. The possible outcomes of proposals are: (a) approved, (b) approved with revision, (c) tabled/rejected, or (d) returned without IRB consideration because it was incomplete or poorly prepared. When your proposal cannot be considered, is tabled, or even approved with revision, your research may be delayed.
9. The IRB will strive to review proposals submitted by the deadline provided in the online schedule of meetings. However, though unlikely, unforeseen circumstances may mean that this is not always possible. The composition of the IRB (and the IRB at any given meeting) is set by law, and if situations occur so that the IRB is not in compliance (e.g., lacks a quorum or key members are absent even with a quorum), it cannot review proposals. It may also be the case that there are too many proposals to review in one meeting. For these reasons – and those noted in #8 – it is important for you to submit your proposal in good time.

10. 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(s) by 1 July of this academic year. If the human participant component of your project is not complete by 1 July of this academic year, you 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.