Guidance - Student Research Involving Human Subjects

Students at the University of South Carolina, both graduate and undergraduate, conduct research with human subjects. The purpose of this guidance is to clarify when student research must be reviewed by the USC Institutional Review Board (IRB).

The USC IRB reviews all projects that meet two criteria: (1) The project must be “research,” and (2) the project must include “human subjects.” The federal regulations provide definitions for each of these terms, and those definitions determine whether IRB review and approval is required.

**Research** is defined as “…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102.d).

**A Human Subject** is defined as “…a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” (45 CFR 46.102.f).

Generally, student research involving human subjects falls into one of two categories: (1) research practica, or (2) directed or independent research project.

**Research Practica (Course and Class-related Projects)**

Research practica are class projects designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, as well as data analysis. Such projects typically are not designed or intended to lead to generalizable knowledge; therefore, this type of activity does not require IRB review.

Data that is collected during research practica projects may be used in independent research projects at a future time. In such a case, the IRB should be consulted, and an IRB application seeking to use existing data may be required.

**Research Projects - Directed or Independent**

Research projects conducted by students that do not fall under the definition of a research practicum (class project), which uses human subjects and is designed to contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, independent research projects conducted in support of honors theses, masters' theses and dissertations. It is possible that a research project may be exempt from ongoing IRB review, but it must meet explicit criteria and the IRB must approve the exemption.

**Responsibility of Faculty Advisors**

Professors and Faculty Advisors have the following responsibilities:

- Ensure that research practica are conducted according to the ethical standards of the relevant discipline.

- Determine when an undergraduate student project does not meet the definition of a practicum and must be reviewed by the IRB. Additionally, it is the responsibility of the faculty advisor to assist students in preparing review materials for the IRB and to ensure that...
the research is conducted in accordance with USC’s agreement with regulatory policy, ethical principles, and applicable institutional policy.

**Potential Practicum Problems**
Students engaged in the process of learning research techniques understandably want to focus on compelling real-life issues; however, the IRB recommends that students avoid topics that may raise concerns for the well-being of the subjects or the students themselves. This includes research projects about illegal activities, sensitive personal behavior, and other areas where a breach of confidentiality may be damaging or harmful.

While practica and other class-related projects are not under the purview of the IRB, the IRB staff is available for consultation with students and advisors.