



**Institutional Review Board
Grants and Research Office**

Procedures for Classroom and Student Research Projects Involving Human Subjects

The University of St. Thomas follows federal regulations and requires that all research involving human subjects with the intent to contribute to generalizable knowledge conducted by faculty, staff, or students affiliated with the University be reviewed and approved by the Institutional Review Board (IRB). Investigations designed to develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, create theories, or generalize findings that may be disseminated beyond the University of St. Thomas. While such research is often disseminated through scholarly publication or presentation of the data, research results do not have to be published or presented to qualify as generalizable knowledge. The intent to contribute to generalizable knowledge makes an experiment or data collection research regardless of publication or presentation. ***IRB approval must be granted prior to any contact with human subjects, regardless of the source of funding and federal status.***

All student research activities involving human subjects must be supervised by a faculty member. Some types of student research activities may not require IRB review beyond faculty supervision because the goal of the research is strictly educational and not intended for generalizable knowledge.

Research Methods Courses and Curriculum Involving Human Subjects

Research projects involving human subjects for which the primary purpose of the research is to be a learning experience in the methods or procedures of research do not meet the federal definition of 'research' and are excluded from IRB review unless the research involves greater than minimal risk, targets vulnerable populations, or involves methods or questions with sensitive, personal, or incriminating topics.

All of the following must be true in order for human subjects research conducted in a classroom setting to be considered outside the purview of the IRB:

- i. The research is a normal part of the students' coursework;
- ii. The primary purpose of the research is the development of the students' skills;
- iii. The research is not pursued in order to publish the results or share at professional and academic conferences, presentations, and gatherings;
- iv. The research is supervised by a faculty member;
- v. The research does not involve greater than minimal risk (*see definition below*);
- vi. The research does not involve any subjects under the age of 18;
- vii. Persons from protected or vulnerable populations, as determined by federal definitions and the IRB office, are not targeted for the research (*see definition below*);
- viii. The research methods or questions do not involve any sensitive, personal, or incriminating topics (*see definition below*).

Definitions of Minimal Risk, Vulnerable Populations, and Sensitive Topics

1. Research involves minimal risk to subjects when the risks of harm anticipated by investigators are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Student research projects that fit the categories below are generally considered minimal risk:
 - a. Research involving the use of educational tests, survey procedures, and interview procedures;
 - b. Observation of public behavior if anonymity is maintained;
 - c. Research with subjects who are elected or appointed public officials or candidates for public office, regardless of whether the subjects may be identified or the information is sensitive;
 - d. Research on individual or group characteristics or behavior in such areas as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, provided that anonymity and confidentiality are maintained;
 - e. Research employing oral history, focus group, program evaluation, or quality assurance methodologies;
 - f. Collection of data through voice recordings for research purposes;
 - g. Research involving the collection or study of existing data, documents, or records if the sources are publicly available or the information is recorded so subjects cannot be directly or indirectly identified.

2. Vulnerable populations include:
 - a. Children
 - b. Pregnant women (the fetus)
 - c. Prisoners
 - d. Educationally disadvantaged populations
 - e. Economically disadvantaged populations
 - f. Adults lacking capacity to consent or with diminished capacity to consent

3. Sensitive Topics: Research involving topics that may cause greater than minimal distress among participants or confidential information that could place a participant at risk if disclosed are considered sensitive topics. Any interview, survey, or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following sensitive topics require IRB review and approval:
 - a. Sexual orientation, sexual harassment, sexual assault, sexual molestation or abuse, incest, practices of contraception, abortion, and/or pregnancy;
 - b. Substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics, any prescription medication legally or illegally obtained;
 - c. Questions regarding mental health (e.g. suicide, depression, obsessive-compulsive disorders, drug use, underage drinking, gambling, and/or eating disorders);
 - d. Traumatic experiences (e.g. being a victim of violence, child abuse, senior abuse, war or combat experiences).

Faculty Responsibility for Oversight of Student Projects or Classroom Research Activities

Each faculty member or department has the responsibility of assessing whether student research involving human subjects or classroom activities involving human subjects require IRB review prior to any contact with human subjects. If the faculty member or department is unsure or untrained to determine whether IRB review is required, they must contact the IRB office for assistance. Faculty members who advise or supervise student research with human subjects are responsible for the oversight of all research activities and ensuring that ethical principles are adhered to by the student conducting research activities.

As of January 1, 2016, faculty members who serve as advisors or supervisors of student research, both undergraduate and graduate, must complete the Collaborative Institutional Training Initiative (CITI Program) education requirement. CITI Program certification is offered through the Institutional Review Board.

Faculty Responsibility in the Classroom

Faculty are encouraged to become familiar with their students' research projects involving human subjects and to assess risk involved in each project (to be educational, this should be done with the student investigator). It is important that instructors who teach research methods courses educate students about Institutional Review Board review and discuss relevant ethical issues surrounding the use of human subjects in research. Instructors of research methods courses may wish to include the CITI Program Training in their assigned coursework.

Independent Research Projects

Independent research projects involving human subjects that employ systematic data collection with the intent of contributing to generalizable knowledge must be reviewed and approved by the IRB prior to any contact with human subjects. All master's qualifying papers, theses, and doctoral dissertations involving human subjects must be reviewed and approved by the IRB.