



Adapted from: Schill, Kelly, Miron, Anca, Verbockel, Sierra. 2016. Standard Operating Procedure 1. UW-Oshkosh

Purpose

The purpose of this policy is to determine whether student research for a class assignment constitutes IRB Review, and does not apply to faculty and staff research.

Definition of Class Assignments

Student class assignments include the following activities:

- Conducted during, or outside of class, with students enrolled in an official course (for credit or not for credit)
- Conducted in fulfillment of class assignments involving interactions with individuals other than the members of the class
- Typically initiated and completed within a single term
- Designed to teach research methods through student interaction with individuals or data about individuals, or designed to help students understand concepts covered by the course
- Generally, not intended to create new knowledge or to lead to scholarly publication

Student projects related to undergraduate honors theses, master's theses, and doctoral dissertations need IRB review if they are determined to be research involving human subjects. Some quality improvement or quality assessment projects that meet the definition of human subjects research also require IRB oversight. To determine if your project will require IRB Review, please complete an IRB Determination of Human Subjects Research Form.

Class Assignments that do NOT require IRB Review

Typically, student class assignments are not considered systematic data collection intended to develop or contribute to generalizable knowledge. This does not meet the federal definition of research and does not constitute IRB Review. IRB Review is not required for research projects conducted for the sole purpose of fulfilling course requirements and results of the assignment are not shared outside the local institution. Projects involving data collection about a company, agency or organization and shared with the entity only, also do NOT require IRB Review. Class projects or practica that involve human interaction for the purpose of training, educational exercises or professional development do NOT constitute research. Student research presented at a campus symposium or celebration of research will NOT require IRB Review IF the project does NOT meet the federal definition of human subjects research.

If documentation of IRB determination is required, submit an IRB Determination of Human Subjects Research Form.

Class Assignments that DO require IRB Review

IRB approval is required when a project meets the federal definition of human subjects research. A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual; or 2) identifiable private information. Student class assignments that are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge meet the federal regulatory definition of "research." Instructors wishing to use class assignments for research purposes must apply to the IRB before assignments can begin.

If students within a course are following the **same** research protocol, a single IRB application form can be submitted by the instructor.

Students conducting individual research projects within a single course will require the submission of a single IRB Course Umbrella Protocol form. Projects covered under a course umbrella protocol must meet the following criteria:

- Be no more than minimal risk and fall under an Exempt or Expedited category of human subjects research
- Not involve any protected or vulnerable populations



- Not involve deception
- Not ask sensitive questions (i.e. drugs/alcohol consumption, sexual activity, illegal activity)

Projects (either individual or course umbrella) that do not meet this criteria require the submission of a standard IRB Protocol application for IRB Review. If a student or instructor decides to use data obtained through a class project for additional research activities, an IRB Existing Data Application must be completed.

Class instructors and students are required to complete human subjects research ethics training through CITI Program before conducting any research.

Instructor Responsibilities

Course instructors are obligated to ensure that students understand their ethical obligations in carrying out their assignments. Instructors should provide guidance to students collecting information in the hopes of minimizing any unintentional risks to students or participants, especially if students will collect private information from protected populations (i.e., children, prisoners, diminished capacity). Risks may include, but are not limited to, physical, psychological or legal harm. Course instructors are responsible for ensuring that administrative permission is obtained prior to conducting research at off-site locations (ex. Private organizations, schools).

If you have questions or are uncertain if your class assignment will require IRB oversight, complete the IRB Determination of Human Subjects Research Form.