

CLASS ASSIGNMENTS GUIDANCE

Wright State University encourages faculty members to develop and utilize innovative classroom activities. Some faculty design class assignments that involve surveys, interviews, focus groups, and/or other interactions with individuals, such as those commonly used in research methods courses. Learning how to conduct ethical human subjects research is an important part of a student's educational experience. In these cases, faculty should consider if such assignments should be reviewed by the Institutional Review Board (IRB) to ensure the protection of human subjects.

The purpose of this guidance to:

- *Clarify when student class assignments fall under the purview of the IRB*
- *Emphasize the instructor's obligation to consider and lessen potential risks to individuals even when the class assignments are not under IRB purview.*

Definition

Student class assignments include activities that are:

- Conducted during, or outside of class, with students enrolled in an official course
- Conducted in fulfillment of class assignments
- 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

IRB Review Not Required

Student class assignments, generally speaking, are not systematic data collection efforts intended to develop or contribute to generalizable knowledge. As such, these activities do not meet the federal regulatory definition of research. Accordingly, student class assignments typically do not fall under the jurisdiction of the IRB and do not require an IRB application, approval, or oversight if all of the following are true:

- Results of the research are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes.
- Results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.).
- Research procedures are no more than minimal risk.
- Vulnerable populations are not targeted (e.g., children under age 18 other than for educational research conducted in school classrooms or other commonly accepted educational setting), prisoners, persons who are cognitively impaired, etc.
- Medical students may only access medical records of patients to which they are assigned. Even though an IRB is not required, HIPAA regulations are still applicable. An

CLASS ASSIGNMENTS GUIDANCE

IRB is required with appropriate HIPAA waivers of authorization in order to access medical records of other patients.

- When appropriate, an informed consent process is in place

IRB Review Required

Student class assignments that are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge (e.g., publish or disseminate data) meet the federal regulatory definition of "research." Independent research projects (e.g., dissertations, theses, honor projects, independent studies) conducted by students also meet the regulatory definition of research. Instructors/student researchers must apply to the IRB for review and approval of these assignments/projects before they begin. Instructors may submit an umbrella protocol that covers all individual projects conducted as part of the class.

If during the course of the classroom assignment, the faculty member or the students discover novel results and change their plans to generalize the data, the project will now meet the regulatory definition of research. If the faculty member or students wish to use the data collected from such class assignments for research and publication, application to the IRB for permission to use the data is required.

Risk Mitigation

Most student class assignments pose little or no risk to students or others. However, instructors should take special care to ensure that students realize the potential for harm and take all possible steps to eliminate the risks to individuals involved in the assignment.

These risks may potentially include:

- physical harm
- psychological harm,
- social harm,
- economic harm, or
- legal harm

Classroom assignments involving data collection with elevated risks to subjects, such as topics involving sexual activity, use of alcohol or illegal drugs, or involvement in illegal activities, need to receive IRB review and approval. Projects involving access to HIPAA protected medical records will also need to be reviewed by the IRB.

Instructor Obligation

Even when a class assignment is "non-research" and, thus, not under the purview of the IRB, instructors have a responsibility to ensure that students understand their ethical obligations in carrying out their assignments. The course instructor is responsible for communicating to the students the ethics of human subjects' research, for ensuring the protection of human subjects

CLASS ASSIGNMENTS GUIDANCE

(including a process in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress. Instructors should provide guidance to students collecting information so as to minimize any unintentional harms to individuals.

Faculty members may use a number of ways to educate students and encourage responsible interactions with others, including:

- Requesting that students take the CITI training on human subject protection before collecting information from others
- Reviewing students' plans for classroom or group projects and suggesting improvements in design and protections for confidentiality
- Explaining ways in which students should be attentive to the physical and psychological welfare of individuals
- Requiring a printed information form that explains the use of the data for coursework only and includes the name and contact number of the instructor
- Requiring, whenever possible, anonymous data collection so that the data are not linked to individuals
- Requiring that information identifying individuals be kept separately from the information collected from those individuals
- Requiring destruction of non-research data at the end of the course or within a short time afterward.