

When does a course assignment require IRB approval?

In support of its teaching mission, Winthrop University encourages novel and innovative classroom activities. Some faculty use course assignments that involve questionnaires, interviews, or other interactions with individuals. This document addresses whether and when such assignments should be reviewed by Winthrop's Institutional Review Board (IRB) to ensure the protection of human subjects.

In accordance with federal regulations, all **research** involving **human subjects** must be reviewed and approved by an IRB prior to any research intervention with a participant.

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (l)).

A **human subject** is a living individual about whom an investigator (professional or student) conducting research 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR 46.102 (e)(1)).

Research vs Course Assignment

Student projects conducted within an academic course may be categorized as either a course assignment or disseminated research. **Disseminated research** includes data that are formally presented to any audience beyond the course (e.g. poster, oral presentation, written paper, seminar, etc.) Course work and independent research projects conducted by students (e.g. theses, honors projects, independent study projects, etc.) that collect data through interactions or interventions with human subjects and will be disseminated must be reviewed by the IRB. If a student project is originally conducted as a course assignment, but develops into disseminated research, IRB approval should be obtained immediately. IRB approval cannot be granted retroactively, and data may need to be recollected for the project.

Student **course assignments** include those conducted during or outside of class by students enrolled in an official course (for credit or not for credit), as well as activities for a course that involve persons not part of the course. For the most part, student course assignments are not intended to create new knowledge or to lead to scholarly publication. Data are gathered without the intention of dissemination beyond the instructor and students of the course. The intent to publish or otherwise disseminate the results of the activity is one clear indication that the activity is "research." Student course assignments generally are not "systematic investigations... designed to develop or contribute to generalizable knowledge" and, therefore, do not meet the federal regulatory definition of "research." If the data collection and interpretation are for pedagogical purposes only and are contained wholly within the course environment, the student project should be categorized as a course assignment. Therefore, as a general rule, student course assignments do not require IRB application, approval, or oversight.

Course assignments involving research activities are considered to be educational in nature, and not subject to IRB review, when all of the following criteria are true. If any one of these criteria is not true, or if the project extends beyond these limitations, then the project should be sent to the IRB for review.

1. The project is limited to surveys/questionnaires/interview procedures, observation of public behavior, or standard educational exercises directly related to the topic(s) being studied in an official University course.
2. Surveys/questionnaires/interviews, if used, contain no sensitive personal questions (e.g., no questions about alcohol/drug use, sexual behavior/attitudes, criminal activity, medical history, grades/test scores) or other personal information that could label or stigmatize an individual. That is, the project involves no more than minimal risk. "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
3. The participants are not from a special population that requires extra protections (pregnant women, prisoners, children under age 18, individuals with impaired decision-making ability, economically or educationally disadvantaged persons).
4. EITHER—information is recorded without any direct or indirect (code number) identifier linking the participant to his/her data—OR—if a direct or indirect identifier is used when recording the data, then the questions being asked could not reasonably harm the participant's reputation, employability, financial standing, or place the participant at risk of criminal or civil liability. The "best" way to handle this is to record the data anonymously without any names or any codes that can be linked to a list of names.
5. The results of the course assignment either do not leave the classroom, or, if the project involves gathering data from or about a company, agency, or organization, the data/results are shared only with that company, agency, or organization.
6. The data will never be published in paper or electronic form. Such activities as presentation (poster, oral presentation, written paper, seminar, etc.) outside the classroom and/or publication lead to generalizable knowledge and thus meet the definition of "human subjects' research."

Faculty/Instructor Responsibilities for Human Subjects Protections

All course assignments that do not fall under the category of disseminated research must still be planned and carried out with consideration of the University's ethical and legal responsibility to protect individuals involved as the subjects of these activities. Instructors should provide guidance to students collecting information so as to minimize any unwitting or unintentional harms to other students or individuals, and to help students understand that they are obligated

to minimize risks to other students or any other people with whom they interact to complete their assignments.

It is the responsibility of the faculty member/instructor to:

1. Discuss research ethics with the class in the context of the assignment prior to intervention with participants.
2. Determine, prior to assigning a project, whether the project is a course assignment or disseminated research.
3. Assure that all students planning to conduct disseminated research involving human subjects submit an application to the IRB in a timely manner. IRBs often request additional information, or require changes, before projects can be approved.
4. Monitor student projects from beginning to end for impact on human subjects. Special attention should be paid to maintaining confidentiality, minimizing risk for participants, assuring freedom to withdraw without penalty, and providing informed consent to participants.
5. Report unexpected adverse effects or complaints involving human subjects to the department chair and to the IRB.

Disclosure to Participants

For course assignments, all surveys/questionnaires/interviews should be preceded by a disclosure of the following points to the respondent.

1. The student identifies him/herself as a student who is performing the activity to fulfill a course requirement, and the course is specifically identified.
2. The name of the supervising faculty member to contact for questions is provided.
3. The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency.)
4. Participants are informed that their participation is completely voluntary, that they can skip any questions they do not wish to answer, and that they can stop answering questions at any time.

Summary

Novel and imaginative classroom exercises help students learn and are integral to high quality teaching. All teaching assignments, however, must respect the rights and welfare of all individuals involved. In accordance with federal regulations, Winthrop University requires that all human subjects' research, as per the federal definitions, be reviewed by the IRB.

Winthrop University recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might be viewed as research. As a general rule, when those activities are conducted solely to fulfill a course requirement, an element of the definition of research (the intent to develop or contribute to generalizable knowledge) is lacking. However, if the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge—an indication of which is intent to publish or otherwise disseminate the data—then the student course assignment is probably research and should be reviewed and approved by the IRB. Also, some course research assignments could place subjects at risk. Therefore, some course assignments may require review by the IRB.