

A memo dated December 6, 2004 to all University of Michigan faculty from the Provosts and the Vice President for Research

When Does a Class Assignment Require IRB Approval?

In support of its teaching mission, the University encourages novel and innovative classroom activities. Some faculty design class assignments that involve questionnaires, interviews, or other interactions with individuals, such as those commonly used in research methods courses. This memo addresses whether and when such assignments should be reviewed by Institutional Review Boards (IRBs) to ensure the protection of human subjects.

The purposes of this memo are:

- To clarify when student class assignments fall under the jurisdiction of the Institutional Review Board (IRB),
- To describe how to seek approval from the IRB when the assignment is under the jurisdiction of the IRB,
- To underscore the obligations of instructors to consider and mitigate potential risks to individuals affected by class assignments even they are not under the IRB jurisdiction.

Student class assignments include those conducted during or outside of class with students enrolled in an official course (for credit or not for credit), as well as activities in fulfillment of class assignments involving interactions with individuals other than the members of the class. These assignments are typically initiated and completed within a single term. Faculty members may design assignments that engage students in interaction with individuals or data about individuals to teach research methods or to help students understand concepts covered by the course. For the most part, they are not intended to create new knowledge or to lead to scholarly publication.

Although most student class assignments pose little or no risk to students or others, some may warrant enhanced attention because of risks to students or to the individuals outside the class. These risks may include physical harm or potential psychological, social, economic, or legal harm, especially when data is collected about sexual activity, use of alcohol or illegal drugs, or involvement in illegal activities. Such risks can be exacerbated when the individuals outside the classroom are minors, pregnant women, prisoners, or people who are otherwise vulnerable, such as cognitively impaired persons. When instructors assign students to collect information about these vulnerable groups, they should take special care to ensure that students realize the potential for harm and take all possible steps to eliminate the risks to these individuals.

NOTE: This policy applies to student class assignments only. Those independent research projects conducted by students, such as theses, honors projects, and independent study projects, that collect data through interactions with living people or access to private information do fall under the jurisdiction of the IRB. Application to the IRB for these student research projects must include an endorsement and acceptance of overall responsibility by a faculty member.

UNIVERSITY POLICY and INTERPRETATIONS

The University policy on oversight of student classroom activities turns on the following determinations, rules, and exceptions:

Determination 1: Student class assignments, as a general rule, are not systematic data collection efforts intended to develop or contribute to generalizable knowledge and, thus, do not meet the federal regulatory definition of "research." Therefore, as a rule, student class assignments do not fall under the jurisdiction of the IRB and do not require IRB application, approval, or oversight.

Determination 2: An exception to Determination 1 occurs when student class assignments are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge. In this case the assignments are, indeed, "research" and do fall under the jurisdiction of the IRB. The intent to publish or otherwise disseminate the results of the activity is one clear indication that the activity is regulated as research. Instructors wishing to use such assignments must apply to the appropriate IRB for review and approval of these assignments before they begin.

See [List of UM IRBs](#) for information about where and how to apply.

In reviewing an application for student research conducted in the context of a course, the IRB may determine that it falls under one of several defined categories of "exempt" research. A declaration of exemption means that, so long as there are no major changes in the research, its conduct does not need to be overseen on a continuing basis by the IRB. A declaration of exemption does not mean, however, that students should act any less professionally or be any less respectful of individuals with whom they interact or about whom they collect private information.

In reviewing an application for research, the IRB may determine that it falls under one of several defined categories of "expeditable" research. Such a determination means that the IRB chair or other designated person may approve a project on behalf of the entire committee. If such an application is well formulated and contains all the information required by the IRB, this process may speed approval. Expediting reviewers may not disapprove a project.

In reviewing an application for research, the IRB may determine that it is neither exempt nor expeditable. In such a case, the application must be reviewed at a convened meeting of the full board.

Class assignments may move from the category of non-research into the category of regulated research if the faculty member or the students change their plans to use the data during the data collection or after the data have been collected. If the faculty member or students wish to use data collected from class assignments for research and publication, application to the IRB for permission to use the data is required.

Determination 3: Even when a class assignment is "non-research" and, thus, not under the jurisdiction of the IRB, faculty members have an affirmative obligation to ensure that students understand their ethical obligations in carrying out their assignments. Instructors should provide guidance to students collecting information so as to minimize any unwitting or unintentional harms to other students or to individuals, especially if students will interact with or collect private information about vulnerable individuals.

Faculty members have used a number of ways to educate students and encourage responsible interactions with others. Depending on the circumstances, faculty may pursue some of the following options:

Reviewing students' plans for classroom or group projects and suggesting improvements in design and protections for confidentiality.

Suggesting that students take the PEERRS on-line training on human subject protection before collecting information from others.

Explaining ways in which students should be attentive to the welfare of individuals in vulnerable situations, such as young children, prisoners, or the cognitively impaired, or when there is any possibility of physical harm.

Explaining ways in which students should be attentive to the welfare in individuals in situations in which students will pose sensitive questions including topics related to sexual activity, victimization, use of alcohol or illegal drugs, or involvement in illegal activity.

When written questionnaires are to be used, suggesting that information be printed on them explaining the use of the data for coursework and including the name and contact number of the instructor.

Suggesting, whenever possible, anonymous data collection so that the data are not linked to individuals.

Suggesting that information identifying individuals be kept separately from the information collected from those individuals.

Suggesting destruction of non-research data at the end of the course or within a short time afterward.

Instructing students about the privacy and security vulnerabilities associated with networked computers.

SUMMARY

Novel and imaginative classroom exercises help students learn and are, therefore, integral to high quality teaching. All teaching assignments, however, must respect the rights and welfare of all individuals involved. The steps an instructor should follow for assigned class activities involving systematic data collection from or about individuals are as follows:

Consider the nature and intent of the activity. 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 classroom assignment is probably research and should be reviewed and approved by the IRB. Follow the requirements of the IRB.

If the intent of the activity is not to develop or contribute to generalizable knowledge but rather to teach research methodology or to demonstrate course material and concepts, then the student classroom assignment is not research and does not require IRB review or approval.

Faculty members should help students understand that they are obligated to minimize risks to other students or to any other people with whom they interact to complete their assignments.

Ask the IRB for guidance when you are unsure. When does a class assignment require IRB approval?