

Are Educational Activities Human Subjects Research?

In the case of a student course-related research project assignment, it may be difficult at times to distinguish between that which would require IRB review and that which is designed simply to provide an experience in research methodology. In some courses, students collect data by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge. In an effort to clarify the matter, the TU Institutional Review Board (TU IRB) has drafted the following guidelines for determining when IRB review and approval is necessary for projects that are part of an academic course:

Student projects that are solely classroom directed exercises (purpose of the student investigation is solely for the fulfillment of a course requirement) do not require IRB review **if they meet all of the following criteria:**

- (a) involves the learning of research techniques; **AND**
- (b) involves no more than minimal risk (the research review category would normally fall under the exempt or expedited review categories as defined by CFR 45 Part 46); **AND**
- (c) the data is recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names, or the recorded data will not identify the subject through their behavior); **AND**
- (d) the data will **not** be used beyond the classroom environment (i.e. will not be published, orally presented, presented at a conference, colloquium, poster presentation or used in further research by the student, other class members or the instructor).

If projects meet ALL of the above criteria, they shall be deemed as "classroom exercises" and are NOT subject to IRB review.

In these cases, the primary responsibility for assuring that the rights and welfare of human subjects are protected is delegated to the faculty member/instructor. The faculty member/instructor shall take responsibility for communicating to students ethical principles of research, review/approve student research protocols prior to initiation of the research project, monitor students' research activities and reports of findings, and assure that the students' own work does not violate human subjects' protection.

If the instructor is not certain that all of the criteria above have been met, they should contact the Coordinator of Research Compliance. If the instructor/student has reason to believe they may wish to present the results of this research in an activity such as a poster presentation or colloquium, the protocol must go before the Board for approval.

*** This policy does not apply to master's theses or doctoral dissertations. Those must follow standard TU IRB review policies and procedures.**

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