

Eastern Illinois University
Policies and Procedures
for the Review of Research Involving Human Subjects

Revised Policy Sections N.1.2 and N.1.3

N.1.2 Student Class Projects

Students may be required in particular courses to conduct projects involving human subjects. The purpose of such projects is not intended to contribute to advances in generalizable knowledge, nor are the results of such activities to be published, presented, or archived. Rather, the function of these class projects is to contribute to the students' individual knowledge and training in a particular academic discipline. Consequently, such projects are not research subject to IRB review as defined by this policy, unless the project places the subjects at more than minimal risk, usually evidenced by one or more of the following:

- Subjects are members of a vulnerable population [children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers)].
- The study asks identifiable subjects about illegal activities (e.g., underage drinking), which may place the data at risk of subpoena.
- The study places identifiable subjects at risk of a breach of confidentiality that may lead to criminal or civil liability, or damage the subject's financial standing, employability, or reputation [45 CFR 46.109(b)(3)].
- The study places subjects at more than minimal risk due to psychologically sensitive subject matter (e.g., interviews covering traumatic events).

Instructors are advised to discuss protection of human subjects with students before the instructional assignment or project begins so that informed decisions can be made about whether IRB review is needed. If even the slimmest likelihood exists that an instructional assignment or project may fall under the definition of research outlined in this document, students should submit a human subjects research protocol to the IRB for review and approval. Please note that IRB approval of a research protocol cannot be granted retroactively under any circumstances.

Even though IRB review may not be required for most class projects, they are subject to faculty oversight as outlined in the following section.

N.1.3 Certification of Courses

When instruction-related research projects involving human subjects are being performed as part of normal course activities, and such projects are not intended to contribute to generalizable knowledge or place the subjects at more than minimal risk (see N.1.2, Student Class Projects), then the instructor must request course certification. This course approval mechanism ensures that human subjects in class projects are nevertheless protected in activities that are not under direct oversight by the IRB.

Instructors who teach such courses must file [Form H](#), Certification of Courses, and the requested additional materials listed on Form H with the Office of Research and Sponsored Programs prior to the initiation of any data collection by students, even though said data is intended for instructional purposes only. Further, an instructor shall not allow student research projects to begin until course certification approval has been received. This form must be submitted every year by the instructor for each course in which instruction-related research is performed. If more than one instructor teaches a section of the same course, each instructor must submit the Certification of Courses Form. Completion and submission by the instructor of Form H and all required materials will designate certification of a course.

The submission of this form will certify to the IRB that the instructor is fully cognizant of the policies of EIU regarding the utilization of human subjects in research. Furthermore, the instructor will hereby certify to the IRB that she/he will exercise reasonable and customary instructional supervision in an attempt to ensure that all class research projects will be conducted in compliance with these policies. Students must conduct only the activities approved by the instructor.

Instructional-related research projects must communicate applicable elements of informed consent (e.g., institutional affiliation of researcher, risk, benefit, voluntary participation, permission to withdraw, etc.) and include appropriate anonymity and confidentiality protections.

Instructors incorporating human subject research projects in their instruction must complete the on-line training program found at: <http://www.eiu.edu/~grants/ConsentTraining/index.html>. In addition, instructors are required to provide training to students in the ethics of conducting research with human subjects via one of 3 options outlined on [Form H](#). This will ensure that students conducting class projects involving human subjects understand, and can apply, ethical principles in human research.

Students must report to their instructor any problems that may arise regarding human subjects as a result of project activities. The instructor must investigate reported problems, and if any harm to a subject has or may occur, the instructor should inform the IRB immediately. The students should cease project activities until it is determined whether or not the project may continue.