Classroom Research Projects Involving Human Subjects

Terms

• Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge....” 45 CFR 46.102(d)

• A human subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information” 45CFR46.102(f)

Review Procedures

• Classroom projects that involve systematic collection of data and for which the objective or design is to develop or contribute to generalizable knowledge are considered research. In other words, if a student plans to use the data outside of the classroom, then the project is considered research. Such projects should be reviewed by the IRB.

• Classroom projects that are designed with the objective of providing students with training about and experience with research methods are not considered research. In these cases, students will not use the data outside of the classroom. Such projects do not require IRB review.

Responsibilities for Course Instructors

• Course instructors are responsible for overseeing the conduct of the project. Instructors have the primary responsibility for ensuring that human subjects are treated ethically.

• Instructors must communicate to students about ethical principles for the protection of human subjects. This includes providing students with training about human subject research through the CITI training course or other acceptable methods (e.g., NIH “Protecting Human Research Participants”).

• Instructors are responsible for guiding their students, and for making the determination regarding submitting materials to the IRB. For example, instructors review projects involving human subjects to see if the project is considered exempt in accordance with 45CFR46.

• Students must submit a copy of any survey instruments or interview questions to the course instructor for review.

• Instructors should contact an IRB Coordinator with any questions regarding a project.