

Classroom Research and Independent Research Projects

Overview

The University encourages novel and innovative classroom activities in support of its teaching mission. Many student class assignments, such as those commonly used in research methods courses, do not meet the federal regulatory definition of 'research.' Therefore, student class assignments ordinarily do not fall under the jurisdiction of the IRB and do not require IRB application, approval, or oversight.

A student class assignment, in general, is:

- An activity designed as part of a course requirement for purposes of learning research methods, such as the consent process or data collection;
- An investigation that a student conducts as a class assignment designed to teach human subject research methodology; and
- A project not intended to produce findings that will be applied more broadly to the population at large.

Parameters for Class Assignments

- VULNERABLE POPULATIONS: The project can include minors or other vulnerable
 populations such as pregnant women, prisoners, those who lack the capacity to consent,
 non-English speaking individuals, etc.; however, the IRB Protocol for Determination of
 Human Research should be submitted to the HSPP in eIRB to take this into special
 consideration.
- NO MORE THAN MINIMAL RISK: "Minimal risk" means 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. This also precludes the study of any illegal activities or
 the collection of private information that could put the participants at risk through a breach
 of confidentiality.
- Projects involving drugs and/or medical devices always require IRB review and approval.

Guidance for Instructors

Whenever class activities involve 'human subjects' but do not meet the federal definition of 'research,' course instructors and their students must be aware of and understand their responsibilities. Course instructors have ultimate responsibility for assuring that the rights and safety of participants are not violated and for the ethical behavior of students when conducting the project. Students need to take personal responsibility and have accountability for their actions as well. The course instructor must personally evaluate each class project and provide supervision and guidance during its conduct.



Classroom Research and Independent Research Projects

Course instructors should ensure the following when evaluating a class project and advising a student:

- The purpose of the proposed project and the procedures to be carried out is practicable and has merit;
- The process by which participants will be recruited does not unfairly target a particular population unless proper justification has been made to do so;
- The participants will be treated with respect;
- The privacy of the participant and confidentiality of the data will be protected;
- The potential risks to individuals are minimized;
- The data collected from participants does not contain identifiable private information when it is not required for completing the class project; AND
- It is best practice to obtain Informed Consent in cases where the participant is asked to complete a task above and beyond their normal duties. The consent should clearly identify the following:
 - The project is being conducted as part of a class project and not identified as a research project;
 - The extent of where/how the information will be used;
 - A description of the procedures involved;
 - That participation is voluntary; and
 - Contact information for the instructor.

Training Requirements for Class Assignments:

It is recommended that all students complete the appropriate CITI human subjects course(s) if they will be conducting a project during the course of a class.

- Instructors assigning class projects are required to complete the required CITI human subjects training program.
- It is recommended that instructors require students to complete the CITI human subjects training program as part of the learning experience, even in cases when student projects do not require IRB approval.

Independent Research Projects

Independent research projects, such as scholarly projects, internships/practica, theses/dissertations, and honors projects may fall under the jurisdiction of the IRB if the information is collected in a systematic manner and there is intent by the student researcher to apply the research findings and conclusions from the study to the population at large.

In the case of the scholarly project, internship, or practicum the student may complete a project on behalf of an organization that would involve interaction with human subjects. The student's primary goal, however, is educational. However, the organization for which the student is volunteering may use the information collected for quality improvement or publication. For purposes of the UA IRB,



Classroom Research and Independent Research Projects

these projects do <u>not</u> constitute research because the student activity is educational, not research. Activities conducted at another site in connection with the internship or scholarly project are subject to the review and approval of the specific site. **Note: Please contact the HSPP if federal funding is involved**.

Conclusion

If a student class assignment or an independent research project is collected in a systematic manner and is intended to be applied more broadly to the population at large, this is Human Research and an *IRB Protocol for Human Subjects Research* must be submitted to the HSPP in eIRB for review and approval **prior** to conducting the study.

For student class assignments that constitute Human Research, the PI must meet PI eligibility requirements. For independent research projects that constitute Human Research, the student's advisor/mentor must be affiliated with the UA.