Guidance: Class Assignments & IRB Review

These guidelines are intended to address whether class assignments meet the definition of research with human subjects and require review by the Institutional Review Board (IRB). Some student class research projects involve questionnaires, interviews, or other interactions with individuals, such as those used in research methods courses. In such cases, faculty should consider if student research projects should be reviewed by the IRB to ensure the protection of human subjects. For questions or additional guidance email irb@southalabama.edu.

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 <u>federal</u> <u>regulatory definition of research</u> (45 CFR 46.102 (I)). The following help further differentiate human subjects research and class assignments.

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)]
- **Generalizable knowledge** is information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.
- **Dissemination** includes but is not limited to presentation at scientific meetings, submission for publication in a scientific journal, and internet postings. Dissemination of the findings also includes presentations at university, state, national, or international settings.
- **Human Subject** is defined as "a living individual about whom an investigator (professional or student) conducting research 1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" [45 CFR 46.102(e)(1)]
- **Student Class Assignment**: For the purposes of this guidance, the following apply:
 - Conducted during or outside of class with students enrolled in an official course (for credit or not for credit)
 - Conducted in fulfillment of class assignments involving interactions with individuals other than the members of the class
 - Typically initiated and completed within a single term
 - Designed to teach research methods through student interaction with individuals or data about individuals, or designed to help students understand concepts covered by the course
 - Generally not intended to create new knowledge or to lead to scholarly publication

Research vs Course Assignment

Student projects conducted within an academic course may be categorized as either a course assignment or disseminated research. Disseminated research includes data that are formally presented to any audience beyond the course (e.g. poster, oral presentation, written paper, seminar, etc.) <u>Course work and independent research projects conducted by students (e.g. theses, honors projects, independent study projects, etc.) that collect data through interactions or interventions with human subjects and will be disseminated must be reviewed by the IRB. If a student project is originally conducted as a course assignment but later develops into disseminated research, IRB approval should be obtained immediately. IRB approval cannot be granted retroactively, and any data collected without IRB approval may not be used outside of class.</u>

Student class assignments

For the most part, student class assignments are not intended to create new knowledge or to lead to scholarly publication. Data are gathered without the intention of dissemination beyond the instructor and students of the course. The intent to publish or otherwise disseminate the results of the activity is one clear indication that the activity is "research."

Parameters for Determining When a Class Project Requires IRB Review

The USA IRB considers classroom assignments involving research activities to be educational in nature and not subject to IRB review when <u>ALL</u> of the following criteria are true:

1. The project is limited to surveys, questionnaires, interview procedures, observation of public behavior, minimal risk experimental studies, or standard educational exercises directly related to the topic(s) being studied in an official university course.

2. Surveys/questionnaires/interviews, if used, contain no sensitive personal questions (e.g., no questions about alcohol/drug use, sexual behavior/attitudes, criminal activity, medical history) or other personal information that could "label" or "stigmatize" an individual.

3. The participants are NOT from a special population that requires extra protections (e.g., pregnant women, people in the criminal justice system, children under age 18, cognitively impaired individuals).

4. The class project does not include any deception.

- 5. Either the information is recorded:
 - i) without any direct or indirect (e.g., race, gender, code number) identifiers linking the participant to his/her data; **or**

ii) no direct identifiers are recorded and any indirect identifiers could not be combined to ascertain the identity of some or all the participants

6. The results of the classroom assignment, including audio and video recordings, either do not leave the classroom, or, if the project involves gathering data from or about a company, agency,

or organization, the data/results are shared only with that company, agency, or organization, and the company will not share the data or results with anyone else.

If any <u>one</u> of the above criteria is **not** true, then the project must be sent to the IRB for review. It is the responsibility of instructor to determine whether a class project involving human participants can be classified as a course-related student project.

Training Requirements

- Students conducting human subjects research must complete the required <u>IRB training</u>.
- Instructors should require students to complete the IRB training tutorial as part of the learning experience, even in cases when the student's project does not have to obtain IRB approval.

Instructors' Responsibilities

- Instructors should meet with students as soon as possible and go over these guidelines to determine if the proposed class project could be considered human subject's research.
- It is the responsibility of the instructor to ensure that the class project is conducted according to the ethical standards of the relevant discipline.
- The instructor must review and approve student IRB submissions in IRBNet, if applicable. The IRB requires the instructor's electronic signature of all student human subjects research projects.
- At a minimum, students conducting class projects determined to be non-human subject's research should use the student class project consent form template. For course assignments, all surveys/questionnaires/interviews should be preceded by a disclosure of the following points to the respondent.
 - The student identifies him/herself as a student who is performing the activity to fulfill a course requirement, and the course is specifically identified
 - \circ $\;$ The name of the supervising faculty member to contact for questions is provided
 - The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency.)
 - Participants are informed that their participation is completely voluntary, that they can skip any questions they do not wish to answer, and that they can stop answering questions at any time.
- If there is remote possibility that a class project may fall under the definition of human subject's research, instructors are advised to submit an inquiry to the IRB Office. Remember, class projects that involve protected populations or collection of sensitive information require IRB review and approval.

We would like to acknowledge the use of IRB guidelines on class-related projects from both Winthrop University and University of Northern Iowa.