

IRB Standard Operating Procedures			
SOP#: 03 Revision#:	Title: Class Projects	Effective Date: March 9, 2018	
Approved By:	Institutional Review Board	Approval Date: March 9, 2018	

## PURPOSE

To clarify when class projects require IRB review and to describe the responsibilities of instructors and students involved in class projects.

## DEFINITIONS

**Class projects** - any collection and/or analyses of human subjects data that are assigned as an educational exercise in the context of a specific course.

**Generalizable knowledge** - information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

**Human subject** - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

**Identifiable private information** - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**IRB** - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

**Minimal risk -** 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.

**Research** means - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

## POLICY

Class projects are designed to teach research methods or to help students understand concepts covered by the course through collection and/or analyses of human subjects data. Class projects may involve a collection of original primary data through intervention or interaction with human subjects. Class projects may also involve analyses of secondary data obtained from human subjects.

Class projects may involve activities that resemble human subjects research; however, class projects are not considered "research" as defined in the federal regulations for the protection of human subjects (45 CFR 46) because they are conducted for training purposes only and do not yield generalizable knowledge.

In an effort to clarify the matter, the IRB has established the following guidelines for determining when institutional review and approval is necessary for class projects:

#### IRB review is not required for class projects that meet <u>all of the following criteria:</u>

- 1. The primary purpose is a learning experience in the methods and procedures of research; AND
- 2. Involve no more than minimal risk; AND
- 3. The project does not include sensitive topics or interaction with vulnerable populations. Observational study and secondary research of protected vulnerable populations can be done with the appropriate protections in place; AND
- The data must be recorded and stored with no <u>direct identifiers</u> (i.e., names, dates of birth, social security numbers, etc.); AND
- 5. Where and whenever possible, the research takes place in a <u>public setting</u> with public access, such as: a classroom, department, dormitory, or other campus setting, a shopping center, park, or street; AND
- 6. The data will not <u>be published or presented outside the university and will not be used in</u> <u>further research by the student, other class members and/or the instructor.</u>

#### IRB review is required for:

- 1. Class projects that do not meet all of the criteria specified above;
- 2. Class projects that may be published or presented outside of the university;
- 3. Independent studies such as honors theses, master's theses, and similar independent research projects. All of these must be reviewed and approved by the IRB before students may begin their research.

# RESPONSIBILITIES

#### Faculty Supervising Class Projects

- Instructors are responsible for ensuring appropriate design and ethical conduct of class projects involving human subjects data.
- Instructors advise students that labeling the class project as "research" is inaccurate and misleading to participants if the research is not intended to be generalizable.

- Instructors advise students to complete training in human subjects protection designated by Northeastern Illinois University's IRB.
- Instructors advise students that data from human subjects must not contain identifiable private information.
- Instructors ensure that students understand what minimal risk means.
- Instructors encourage students to use Appendix Decision Tree for Class Projects for determining whether their project needs IRB review.
- Instructors encourage students to use Appendix Class Project Consent Form for informing participants about the project and obtaining their permission prior to their participation in the project.
- Instructors closely monitor class projects to ensure that students are following correct procedures and conducting the project as was proposed.
- Instructors intervene and discuss the future of student projects should they change in any way from what was originally proposed.
- Instructors, to the best of their ability, monitor the student projects and assure the projects are not shared, presented and/or published outside the NEIU community, or submitted into NEIU's repository without prior approval from the IRB. Should this occur, the instructor is to contact the IRB immediately.

#### Students

- Students are responsible for following the guidelines for class projects as outlined in the course syllabus.
- Students participating in class projects are required to take and pass training in human subjects protection designated by Northeastern Illinois University's Office of Research and Sponsored Projects.
- Students obtain verbal or written consent from participants to ensure voluntary participation in class projects when applicable
- Students inform participants that their data will be destroyed after the class project is completed (end of the semester).
- Students must notify their instructor immediately regarding any changes to originally proposed project.
- Students do not share, present and/or publish any part of the class project outside the NEIU community without prior approval from the IRB.

## Regulations

45 CFR 46.102

### **Author Reference**

NEIU IRB George Mason University SOP "Classroom Projects"

#### **Contact Information**

Please direct questions or concerns about this policy to:

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#### Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.