



Northeastern University

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HSRP Policies and Guidelines

Office of Human Subject Research Protection

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# Policy for classroom research involving faculty and students

Office of Human Subject Research Protection, Northeastern University

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## POLICY FOR CLASSROOM RESEARCH INVOLVING

### FACULTY AND STUDENTS

#### A. Introduction

This guideline addresses students conducting research. The Northeastern University IRB (NU-IRB) is guided by [45 CFR 46](#) (Common Rule) in its definition of research as being a “systematic investigation designed to develop or contribute to generalizable knowledge.” The IRB distinguishes between research conducted in a classroom as part of the learning experience (“Student Research”) from research conducted to add to generalizable knowledge or a professional body of knowledge (clinical research, thesis, or dissertation work). The purpose of this policy is to clarify when student research must be reviewed by the IRB, or if it is deemed as “Student Research,” who is responsible for reviewing that research.

#### B. Definitions

1. **Dissemination** means the distribution of findings and includes, but is not limited to, masters and doctoral theses/dissertations, presentation at a scientific meeting or conference, submission to or publication (paper or electronic) in a scientific journal, and posting on the Internet.

2. **Human subject** means 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.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3. **Institutional Review Board (IRB)** means the Northeastern University board which reviews and approves the initiation of, and conducts periodic reviews of, research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

4. **Minimal risk** means that 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 of healthy individuals.



5. **Student Research** means any observation or intervention, including administration or survey or interview questions, by a student as part of a course which is designed to develop or contribute to student learning or class discussion, but which will not lead to generalizable knowledge or publication/dissemination of findings outside of the classroom.

6. **Student Researcher** means any student enrolled in a course at Northeastern University who conducts research on human subjects as an assignment or project within a course, excluding a master's or doctoral theses research which must be under NU-IRB procedures.

### C. Policy

1. Student research projects that meet ALL of the conditions stated below may be conducted under the supervision of the faculty member without submitting a protocol to the IRB.

2. Projects that do not meet all of these conditions must be submitted to the IRB for review. [http://www.northeastern.edu/research/research\\_integrity/human\\_subjects/](http://www.northeastern.edu/research/research_integrity/human_subjects/).

Research conducted by students, graduate or undergraduate, as a part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to or likely to lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis). In such cases, the classroom project does not require NU-IRB submission and approval.

a. The class project must meet the definition of classroom research/student research. This is defined as a project which:

- is a normal part of the student's coursework;
- is supervised by a faculty member;
- has as its primary purpose the development of the student's research skills;
- does not present more than minimal risk to participants or to the student investigator;
- does not include any persons as research subjects under the age of 18;
- does not include any persons as research subjects who are classified as part of a vulnerable populations according to Federal regulations (see below);
- is not "genuine research" that is expected to result in publication or some other form of public dissemination;

NOTE: This policy applies to student class assignments only. Those independent research projects conducted by students, such as theses, honors projects, and independent study projects, that collect data through interactions with living people or access to private information DO fall under the jurisdiction of the IRB. Application to the IRB for these student research projects must include overall responsibility by a faculty member who will be named as the Principal Investigator of the project.



b. Student research projects must meet all the criteria for an Expedited Review as defined in the Federal Regulations: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>. If the faculty member has concerns or doubts, he/she should consult with the Office of Human Subjects Research.

c. Please note that *even if the intent is to not produce generalizable knowledge, if a special population or sensitive topic area is part of the project, the student's project cannot qualify for general approval and, therefore, DOES require NU-IRB approval.*

Categories of sensitive information include information:

- 1) Relating to sexual attitudes, preferences or practices;
- 2) Relating to use of alcohol, drugs or other addictive products;
- 3) Pertaining to illegal conduct;
- 4) That if released could reasonable damage an individual's financial standing, employability, or reputation within the community;
- 5) That would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- 6) Pertaining to an individual's psychological well-being or mental health;
- 7) Genetic Information.

Categories of special subject population:

- 1) Minors (under eighteen years of age).
- 2) Fetuses or products of labor and delivery;
- 3) Pregnant women (in studies that may influence maternal health);
- 4) Prisoners;
- e) Individuals with a diminished capacity to give informed consent.

d. Faculty teaching research methods and overseeing student research projects are expected to understand the philosophy, ethics and practice of protecting human subjects in research; to adhere to these principles during the conduct and supervision of classroom research projects; and to teach these practices and principles to students. Faculty will be responsible for ensuring that all student research projects are conducted in accordance with federal regulations and principles regarding protection of human subjects in research.

e. Faculty who will be Principal Investigators on classroom research projects must complete the NIH Computer-Based Training module which may be found at the following address: <http://phrp.nihtraining.com/users/login.php>.

### **3. Thesis/Dissertation Research**

Thesis and dissertation projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the NU-IRB.



## D. Tips for Faculty

Please note that, consistent with University policy, all teaching assignments involving human subjects must respect the rights and welfare of all individuals involved. The following suggestions for the faculty members provide guidance concerning student classroom projects:

**1. Consider the nature and intent of the activity.** If the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge -- an indication of which is intent to publish the data -- then the student classroom project is probably research and needs to be individually reviewed and approved by the IRB.

**2. IRB approval cannot be made retroactive.** If there is any likelihood that the results of the project might later be used for research that does lend to generalizable knowledge (for example, a presentation to a group other than the class), IRB approval must be sought prior to conducting the research. IRB approval cannot be granted retroactively.

**3. Minimize risks whenever possible.** Faculty members should help students understand that they are obligated to minimize risks for human subjects with whom they interact during the completion of their assignments. Depending on the circumstances, faculty members may find some of the following suggestions for students helpful:

- Have students take the NIH on-line training on human subject protection before collecting information from others.
- Encourage the use of anonymous data collection so that data is not linked to specific individuals.
- Have information identifying individuals kept separately from the information collected from those individuals.
- Collect project data at the end of the course, or within a short time afterward, and request all copies in the student's possession be destroyed.
- Encourage the use of unsigned consent forms.

**Ask for help!** Ask the Office of Human Subject Research Protection for guidance when you are unsure of what review process is needed for a student classroom project. Their contact information may be found at [http://www.northeastern.edu/research/research\\_integrity/human\\_subjects/](http://www.northeastern.edu/research/research_integrity/human_subjects/). Or you can call Nan C. Regina, Director of the Office of Human Subject Research Protection at 617-373-4588.