# Guidance: Defining human subject research

## Overview

The Human Research Protection Program (HRPP) supports research involving humans and works with investigators and students on conducting work appropriately, and the Institutional Review Boards (IRB) review and approve research as required. The HRPP and the IRB follow the federal definitions of regulated *research* and *human subjects*.

Undergraduate class projects and research methods classes may involve data collection activities for instructional purposes that do not require IRB review and oversight because the goal is to teach methods and prepare the student for future research, not to contribute to generalizable knowledge. This guidance provides definitions used in the regulations, examples of research, and the distinction between human and not human research.

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

**Systemic investigations** may include data, such as the following examples:

- Surveys and questionnaires
- Interviews and focus groups
- Evaluation of social or educational programs
- Cognitive and perceptual experiments

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**Human subject** means a living individual about whom an investigator, including students, is 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 or identifiable specimens.

Regardless of whether your research study meets the federal definitions of research and human subjects, it is imperative that the three elements detailed in the Belmont Report are applied. This will ensure research participants are treated with respect and that their rights and welfare are considered during every stage of the research.

## Northeastern University (NU) subject research policy

It is the policy of NU that no activity involving human subjects be undertaken until those activities have been reviewed and approved the by University's IRB. Accordingly, all proposals for university research involving human subjects must first be submitted to the OHSRP for IRB review and approval.

This policy applies to all research involving human subjects conducted by faculty, staff, and/or students at the University regardless of the source of funding or location of the activity.

## Class assignments about research that will not need IRB

The NU Policy on classroom activities including human subjects conducted by students, graduate or undergraduate does not usually fall under the federal definition 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 IRB submission and approval.

However, if a class or student research activity falls under the federal definitions of *regulated research* and *human subjects,* or if the goal or initial intent of the activities are to collect data to be used beyond the classroom, a formal review and approval by an IRB will be necessary.

Some types of student research projects involve collecting information from people, but do not meet the regulatory definition of IRB-regulated research and **IRB review is not required.** Examples include projects designed to:

- Tell an individual's story (oral history interviews, biography or other journalistic interviews)
- Collect information about organizations and not individuals
- Looking at information from data sets like those that are publicly available (census data) or they have access to like something shared data by an advisor
- Analyzing documents like personal journal entries or homework assignments
- Results of the research will be viewed and discussed within the classroom for teaching

and learning purposes.

- Results of the research will be shared in an undergraduate research symposium with the clear indication that the work was completed as a class assignment and does not fall under the definition of human subject research and therefore was not approved by the IRB.

## Class Assignments or research that *will* require IRB review

- Results of the research will be shared through public presentations or published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal).
- Interacting with study participants by way of surveys, focus groups, or interviews
- Observations like classroom settings or public places like a neighborhood park

## Required human research training

Under the direction of the Office of the Vice Provost for Research, NU requires the completion of training on the protection of human subjects and the ethical principles of research for all human research, regardless of whether or not investigators have received funding to support their project. This training is mandatory for all faculty, staff, and students who conduct/supervise human research whether on campus or off-campus.

If you have completed HSR training, please provide documentation. Documentation is only required to be submitted once and may be provided with your IRB protocol application. The OHSRP will accept documentation of human subject protection training from other institutions. If you have not yet completed some type of human subject protection training, Northeastern University has an account with CITI. All NU affiliates can take this course at no charge. Please note that approval for training is for 3 years. Those who continue to be engaged in HSR will be instructed to complete a refresher course.

## Identifying a faculty advisor to serve as the PI

An initial criterion to submit an IRB protocol is to identify a faculty advisor or course instructor to serve as the lead Principal Investigator (PI) for the research study. At Northeastern University (NU), a student researcher cannot be listed as the study's PI. This protects the student as their research efforts are part of their overall learning at NU.

## Instructor and advisor role

The trained and experienced PI will mentor and provide oversight during the entire research lifecycle. More importantly, a trained and experienced PI should be able to identify potentials risks and know what to do when something unexpected occurs. The student researcher should also have the met the educational requirements and have adequate training for any study

procedure they perform. A class instructor or advisor/PI should make this assessment. For example, one must have certain training to draw blood from another person; assessing suicidal ideation and self-harm, etc.

## Responsibilities of instructors for class assignments

- Has an obligation to ensure that students understand their ethical obligations in carrying out their class assignments.
- Has responsibility for teaching students about the ethics of human subjects research. If desired, instructors for class assignments that do not need an IRB protocol may still assign students all or portions of the widely used CITI training program. This is free of charge with all faculty members, instructors, students and staff affiliated with NU. The user simply needs to indicate NU as their affiliated institution and they will have access to all training modules.
- Assumes responsibility for ensuring the protection of human subjects involved including a process for obtaining voluntary informed consent when appropriate.

## Responsibilities of advisors/PI for research requiring IRB review

- Takes ultimate responsibility for the protection and rights and welfare of human subjects, the conduct of the study, and the ethical performance of the project
- Responsible for mentoring their student researchers regarding ethical principles for the protection of human subjects, which includes completion of the CITI training courses.
- Complies with all NU policies and procedures and all applicable federal, state, and local laws.
- Responsible for reviewing and making the final determination regarding materials to be submitted to the IRB, including any survey instruments or interview questions.
- Ensures the correct information provided in the IRB application is complete and accurate.
- Ensures the project will be performed by qualified personnel according to NU IRB-approved protocol.
- Any unanticipated incidences or protocol deviations are reported to the OPRS and IRB in a timely manner.

Instructors should consider whether IRB review and approval will be needed as they plan class assignments involving research activities or undergraduate research projects. If in doubt consult with the Human Subject Research Protection office at IRBreview@northeastern.edu.

## Guidance on informed consent

The Belmont Report identifies three principals that apply to human subject research: (i) respect for persons; (ii) beneficence and (iii) justice. The Belmont Report informs us that for research to be ethical, individuals should have the choice to participate in the research after

being full informed of all study components (respect for persons), that the benefits of the research out-weigh the risks associated with the research (beneficence), and that the selection is equitable (justice).

Even if the data collection activity is for a class assignment only, individuals that are asked to be part of a study should be aware of what is being asked of them, that it is their choice to volunteer, and their decision to drop out even after agreeing to be in the study. These individuals must also be told what will happen to the data they provide, who else may see this information, and how long their identifiable information will be retained.

Furthermore, individuals must be told how long participation will take and any possible negative consequence they may faces. Imagine a research protocol that involves asking participants about past trauma. The researcher must be prepared for participants to have negative memories surface. For example, it is not sufficient to just tell a participant they will be interviewed for an hour. Researchers should provide example questions and tell them that the interview may remind them of negative memories. Doing so allows the individual to make a fully informed choice of participating. One way to share all of this with the potential participant is to have a verbal consent plan or participant information sheet. Studies that are not defined as human subject research should still have some type of consent process to ensure one understands that it is their choice to participate as well as their choice to withdraw at any time.

It is easy to identify risks when we think of biomedical studies and the types of interventions that are asked of research participants. Social and behavioral research also may have risks involved, and although they are often lower than the biomedical studies, they should not be disregarded or ignored. It is impossible to predict every unexpected incident or problem. What is possible is to think about what potential risk a participant may experience. Asking someone about traumatic events may trigger certain behavior or negative thoughts and/or memories. However, the risk of being in the study is not their past trauma but rather the questions that are asked of them during the study.