Northeastern University
Human Research

Guidance: Defining human subject research

Overview

The Department of Human Research (DHR) supports research involving humans and works with investigators and students on conducting work appropriately, and the Institutional Review Board (IRB) reviews and approves research as required. The DHR and the IRB follow the regulatory 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. (For more details, see our guidance on Capstone Projects & Undergraduate Research.) This guidance provides definitions used in the regulations, examples of research, and the distinction between human subjects research and not human subjects research.

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

Systematic investigations may include data collection, such as the following examples:

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

Your project is likely designed to develop/contribute to **generalizable knowledge** if you intend on sharing the information you produce with others (e.g., as a poster presentation, as a conference talk, or as a publication). (For more details, see our guidance on Research Activities vs Quality Improvement or Assurance.)

Human subject means a living individual about whom an investigator conducting research (including students) either:

(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 project meets the regulatory definitions of **research** and **human subjects**, it is imperative that the three principles 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 project.

Northeastern University (NU) human subjects 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 DHR for IRB review and approval.

This policy applies to all research involving human subjects conducted by those eligible to serve as PI, regardless of the source of funding or location of the activity. Northeastern has guidance on who is eligible to serve as PI.

Class assignments about research that will not need IRB review

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 regulatory definitions of *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. (For more details, see our guidance on Capstone Projects & Undergraduate Research.)

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. See Human Subject Protection Training & Outreach for more details.

Identifying an eligible Principal Investigator

An initial requirement to submit an IRB protocol is to identify a faculty member or other eligible individual 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 without an exception. This protects the student as their research efforts are part of their overall learning at NU.

PI: 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 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 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 incidents or protocol deviations are reported to the DHR 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 Department of Human Research 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 face. 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.