



Guidance: Capstone projects & undergraduate research activities

Overview

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

Undergraduate class assignments and/or Capstone graduation projects generally do not require IRB review and oversight because the goal is to teach methods and prepare the student for future research. They do not fall under the federal definitions of human subject research as they are not intended to or likely to contribute to generalizable knowledge. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures.

Expectations for Classroom and Capstone Projects

Per NU Policy classroom activities including human subjects conducted by students, graduate or undergraduate do not usually fall under the federal definition of research. However, ethical principles should always be integrated into all activities conducted at Northeastern University even when not required by the federal regulations.

1. Ensure the risk to the participant and investigator is minimal. It may not meet the classroom assignment criteria if:
 - a. Collecting identifiable data about sensitive topics such as sexual history, drug use, abuse, physical or mental health conditions, or other data that could be emotionally or socially sensitive.
 - b. Conducting Procedures that present a physical risk such as blood draws, x-rays, or experimental devices that haven't been commercially evaluated for safety.
2. Do not collect identifiers unless necessary. If necessary for research, minimize identifying information collected to only those needed to conduct the research. Often this means not collecting names, birthdates, or student ID numbers unless the project's design explicitly requires it. When identifiers are needed, steps to ensure that this data is secured and destroyed should be taken. This includes a clear chain of custody for data, a plan to identify where all copies of the data are stored, a plan to ensure others don't have access to any devices or platforms where data is stored, and a plan to destroy this data as soon as the data is no longer required to conduct the activity.
3. Data for the project should be destroyed as soon as the project is completed. Information that is stored as part of the student's academic record can be retained, but



- the raw data not related to the academic record should be destroyed.
4. Unless the student/faculty is qualified to do so, studies should not involve vulnerable populations. Additional appropriate protections must be put in place.
 5. A plan for participant consent should be implemented. This includes ensuring that the consent process:
 - a. Discloses that they are a NU student who is performing the activity to fulfill a course/capstone requirement, and the course is specifically identified.
 - b. Explains to prospective participants of all aspects of the research: study procedures, duration, who will have access to their data, how data will be used/shared, and when data will be destroyed.
 - c. Explains the steps to protect participant privacy and confidentiality during all steps of the research project.
 - d. Does not promise benefits (individual or scholarly) that are not likely to result.
 - e. Includes contact information for the supervising faculty member if any concerns are raised.
 6. Ensure that participation is voluntary. This includes:
 - a. Ensuring that recruitment does not leverage or use any existing relationships between the faculty and/or students' researchers to recruit participants unless there is a clear and explicit reason for why alternative recruitment methods can't be implemented. This includes students recruiting their own friends and/or family.
 - b. Ensuring that any compensation provided is not coercive given the population being recruited.

Faculty Responsibilities

Faculty 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. Faculty will be responsible for:

1. Ensuring that assigned projects involving humans can be classified as a course-related student project under the criteria provided
2. Ensuring that all student research projects are conducted in accordance with federal regulations and principles regarding protection of human subjects in research.
3. Ensuring that the students are adequately trained and that their planned research activities are designed with appropriate and adequate safeguards in place to ensure that the activities are within the scope of ethical conduct.

Capstone projects intended to contribute to generalizable knowledge should explicitly justify why an exception is warranted when seeking review.