Northeastern University
Human Subject Research Protection

Guidance: New investigators conducting human subject research

Welcome to Northeastern University! The Office of Human Subject Research Protection (OHSRP) and the Institutional Review Board (IRB) look forward to working with you to approve your research projects that include human participants. The OHSRP /IRB is a university-wide integrated office supporting human research on all Northeastern University (NU) campuses.

To assist you in the transition to our university we have drafted guidance and provided resources and reference links. Our team is also happy to meet with you one on one to discuss your project and to guide you in preparing and submitting the materials for IRB review.

NU human 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.

When is IRB review required?

When a planned activity meets the definitions of "research" and/or "clinical investigation" involving a "human subject," the regulations regarding the protection of human subjects apply.[1] According to NU requirements, human subject research must be approved by the IRB or determined to be exempt from the OHSRP office before engaging in any human research activity, including contact with human subjects or data collection. Refer to our Guidance Library for additional information on *Definitions and terms used in human subject research* and the IRB *Review types and processes*.

Types of research activity that require NU IRB review (or cooperative agreement) include, but are not limited to:

- Enrolling/consenting human subjects into research studies occurring at NU or another institution.
- Collecting data through interaction or intervention with participants at NU or another institution.
- Analyzing previously collected data that includes private, identifiable information.

[1] Definitions of these terms are included at the end of this document.

- Analyzing previously collected identifiable human materials (specimens).
- Receiving a federal grant even when all activities will be conducted by subawardees.

Researchers can self-determine whether their activities meet the definition of human subjects research. If you are unable to determine whether your activities meet the regulatory definition of human subjects research, OR if you need the IRB to provide an official determination that your activity is not human subjects research, complete a Human Subject Determination form and submit it to **IRBReview@northeastern.edu**.

***NOTE**: The IRB can only make this determination **PRIOR** to the beginning of the activity. The IRB will not make a determination after the activity has already begun.*

Considerations for existing research studies

If you are planning to continue human research projects approved by a previous institution (e.g., interacting and/or intervening with subjects, obtaining and/or analyzing private identifiable data about subjects or identifiable biospecimens), this activity needs to be reviewed by the NU IRB or a reliance agreement is needed.

Reliance agreements

If the project will continue to receive IRB approval at your previous institution, it may be possible to rely upon the previous institution's IRB approval after consideration of several factors (e.g. funding, lead institution, location of research procedures). For additional information, you may refer to the document titled, Establishing reliance agreements in our Guidance Library.

New faculty should not continue to engage in human subject research, including analysis of personally identifiable data or specimens, until:

1) The study has NU IRB approval or an exempt determination has been made, **OR**
2) A reliance agreement has been established and signed by both institutions.

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.

Classroom activities

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.

The Human Subject Determination form will help identify if the activities require an IRB protocol. If you are unable to make a determination, please reach out to our office. whether a classroom activity meets the regulatory definition of human subjects research please refer to the

Reach out to us at anytime

The OHSRP office can be reached at IRBReview@northeastern.edu. *Helpful tips when submitting an IRB application* can be found in our Guidance library. Our website also provides the forms and instructions for submitting, templates, FAQs and other resources.

We look forward to partnering with you on your research efforts at Northeastern!

Resources

Code of Federal Regulations

Department of Health & Human Services (DHHS)

Food and Drug Administration (FDA)

NU's OHSRP that includes: Guidance, IRB applications & other submission forms; NU Policies; and Templates

HHS definitions

Research, is 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

You are developing/contributing 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).

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.

FDA definitions

Human Subject is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen an investigational device is used. A subject may be either a healthy human or a patient. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

Clinical Investigation means any experiment that involves a test article and one or more human subjects and either is subject to requirements for prior submission to the FDA under section 505(i), 507(d), or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of Part 58 of this chapter, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations.