

RESEARCH

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Related Policies: Code of Ethical Conduct; Policy on Research Misconduct; Policy on Responsible Conduct of Research; Policy on Classroom Research Involving Faculty and Students

Responsible Office/Department: Office of Human Subject Research Protection

Keywords: Human subject; Institutional Review; IRB

Policy on Human Subjects Research

I. Purpose and Scope

Northeastern University is committed to the ethical conduct of research, and strives to adhere to the highest ethical standards for the protection of human subjects, consistent with the principles of the Nuremberg Code and the Belmont Report. Accordingly, the University has established the Office of Human Subject Research Protection (HSRP), which provides central administration for the University's Institutional Review Board. The Institutional Review Board provides a procedural framework for meeting the ethical and legal requirements that the rights and welfare of human subjects receive adequate protection.

This policy applies to all research involving human subjects conducted by faculty, staff, and/or students at the University, except that research conducted or assigned as part of their coursework is governed by the Policy on Classroom Research.

II. Definitions

For purposes of this policy,

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subjects as defined under federal regulations, 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." 45 C.F.R. § 46.102.

Investigator or principal investigator means any individual who is involved in conducting human subjects research studies, including without limitation those performing various tasks related to the conduct of human

subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.

III. Policy

It is the policy of Northeastern University that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB). Accordingly, all proposals for university research involving human subjects must first be submitted to the Office of Human Subject Research Protection for IRB review and approval.

In addition, Northeastern University requires completion of training on the protection of human subjects and the ethical principles of research for all human subject 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 research involving human subjects whether on campus or off-campus, whether funded or unfunded.**

The principal investigator is responsible for the protection of participants in human subjects research. Safeguarding the participants from undue risk is the ethical responsibility of each person who is involved, either directly or indirectly, in conducting research at Northeastern University. Principal Investigators must require that each member of the research team carries out all research procedures in accordance with ethical principles of research.

The faculty at Northeastern may not recruit students from their own classes for their faculty research projects.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with harm to subjects. Investigators whose research does not comply with university policies may not obtain HSRP review or approval for other human subjects research activities for themselves or their students until the compliance issues have been cleared. Regulations require that HSRP report violations of university policies or federal regulations to the appropriate officials.

Information regarding approval procedures and other necessary guidelines for human research at the University are found at the HSRP website, in *Policies and Procedures for Human Research Protections* at <http://www.northeastern.edu/research/hsrp/manual/>. Investigators are responsible for adhering to the guidelines provided, and should read the *Policies and Procedures* prior to submitting an application for review.

IV. Additional Information

Performing research with human subjects without prior IRB approval is unethical and illegal. Moreover, any violation of research guidelines by the university or an investigator jeopardizes the University's

Federal Wide Assurance agreement approved by the United States Department of Health and Human Services, and threatens the University's federal funding. A project that is conducted without IRB approval is subject to termination and/or other action by the University, and may be subject to disciplinary action up to and including termination or separation, and/or criminal or civil legal action.

V. Contact Information

For information about human subjects research and the procedures for applying for IRB review, visit the HSRP website: <http://www.northeastern.edu/research/hsrp/> or call (617) 373-4588.

Research participants with questions may contact HSRP via telephone at (617) 373-4588, or via email at n.regina@neu.edu.