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. Accordingly, all university research involving human subjects must first be reviewed by the Office of Human Subject Research Protection.

**Required Training for Research Involving Human Subjects**

Under the direction of the Office of the Vice Provost for Research, Northeastern University requires completion of the NIH Office of Extramural Research training for all human subject research, regardless of whether or not investigators have received funding to support their project. The online course titled "Protecting Human Research Participants" can be accessed at the following url: [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php).

1.0 **Goals of Institutional Review Board**
2.0 **Responsibilities of the Investigator**
3.0 **HIPAA & Health Information Privacy Laws**
   3.1 **State Law**
   3.2 **Identifying HIPAA-Covered Studies**
   3.3 **Individuals' Access to Protected Health Information (PHI)**
4.0 **Exceptions to HIPAA's Authorization Requirement**
   4.1 **Use or Disclosure of "De-Identified" Health Information**
   4.2 **Limited Data Set**
5.0 **What Research Requires Review?**
6.0 **Procedures for Submitting Proposals for Review**
7.0 **Review Process**
   7.1 **Initial Review**
   7.2 **Studies Categorized as Exempt or Expedited**
   7.3 **Projects Requiring Full Committee Review**
   7.4 **At the IRB Meeting**
   7.5 **IRB Actions**
   7.6 **Time Frame for Review**
8.0 **Student Research Proposals**
   8.1 **Classroom Research Involving Faculty and Students**
   8.2 **Students as Subjects**
9.0 **Research involving Children**
   9.1 **Obtaining assent/parental permission**
   9.2 **Withdrawal**
10.0 **Other Vulnerable Populations**
11.0 **Diversity in Research**
12.0 **Health Information Privacy Addressed by Informed Consent and Health Information Use and Disclosure Authorization**
13.0 **Continuing Review Procedures**
14.0 **Modifying/Changing an Approved Protocol**
15.0 **Adverse Events**
16.0 **On Site Monitoring**
17.0 **Suspension or Termination of Approval**

**Appendices:** [Forms and Instructions](#)
1.0 GOALS OF THE INSTITUTIONAL REVIEW BOARD (IRB)

- Protect the rights of human subjects who participate in research conducted by faculty, staff, and students of Northeastern University.
- Assess the risks and benefits of proposed research, and ensure that risks to human subjects are kept to an absolute minimum and are justified by potential benefits of the research.
- Ensure the confidentiality of information obtained from research subjects to the extent allowed by law.
- Ensure that, where appropriate, an Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization is obtained from each research subject.
- Facilitate high quality research at Northeastern University.
- Create a cooperative process, encouraging dialogue with researchers.
- Comply with applicable state and federal privacy laws.

2.0 RESPONSIBILITIES OF INVESTIGATORS

The principal investigator’s primary responsibility in human subjects’ research is to ensure that the rights and welfare of the participants are protected. 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.

Investigators must assure that each member of the research team carries out all research procedures in accordance with ethical principles of research. These principles of Justice, Autonomy and Beneficence are set forth in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* and are codified as regulations in *Title 45 Code of Federal Regulations Part 46*. Investigators are strongly encouraged to read these and other relevant documents available at the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) web site.

As an integral part of ethical conduct of research, federal guidelines require an independent review of protocols involving human subjects before an investigator can begin the study. This is true at all research institutions, such as Northeastern, that receive federal funding for such research. This independent review process provides an unbiased evaluation of the risks, promotes the safety of research participants and documents that the research, when conducted as approved, will be in accordance with federal regulations.

At Northeastern, the Office of Human Subject Research Protection (HSRP) and the Institutional Review Board (IRB) serve this independent review function. *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).*

Information regarding approval procedures and other necessary guidelines for human research at the University are found in this document, *Policies and Procedures for Human Research Protections*. Investigators are responsible for adhering to the guidelines provided here, and should read it prior to submitting an application for review.

Protocol reviews are prospective. No retrospective approvals can be granted. *Performing research with human subjects without prior IRB approval is unethical, illegal, and may jeopardize the rights and"
welfare of participants in research. A project that is conducted without IRB approval is subject to termination or other action by the University.

In order to receive federal funding for research with human participants, Northeastern University must have a Federal Wide Assurance (FWA) approved by the United States Department of Health and Human Services. In this signed agreement, Northeastern University assures the federal government that all university research will be conducted in accordance with federal regulations for research. Any violation of research guidelines by the university or an investigator jeopardizes this agreement and threatens the University’s federal funding.

These federal regulations are the minimal standards for research. State laws or University policies may impose additional requirements as deemed appropriate, but may not decrease requirements. Northeastern University’s FWA number is 4630.

3.0 HIPAA & Health Information Privacy Laws

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its privacy regulations create privacy obligations that may impact academic researchers conducting studies involving human subjects. The provisions apply to individually identifiable health information, or “protected health information,” in certain circumstances (discussed below). The HIPAA provisions add an additional layer of regulation to the Federal Policy for the Protection of Human Subjects (also known as the “Common Rule”) and to FDA regulations - HIPAA does not replace them.

3.1 State Law

HIPAA does not preempt state laws that set forth health information privacy standards that are more stringent than those established by HIPAA.

3.2 Identifying HIPAA-Covered Studies

A researcher may be a HIPAA-covered health care provider if he or she furnishes health care services to individuals, including the subjects of research, AND transmits any protected health information in electronic form in connection with a “standard transaction” (defined below). “Health care” is broadly defined under HIPAA and includes, but is not limited to, the following activities: preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care and counseling; physical therapy; occupational therapy; assessment or procedures with respect to the physical or mental condition or functional status of an individual or that affects the structure or function of the body. If a researcher’s study may involve the provision of health care, the researcher must describe the activities that may constitute health care within the Application for Approval for Use of Human Participants in Research.

HIPAA’s standard electronic transmissions include those involving health care claims or equivalent encounter information, health care payment and remittance advice, coordination of benefits, health care claim status, enrollment and disenrollment in a health plan, eligibility for a health plan, health plan premium payments, referral certification and authorization, first report of injury, and health claims attachments.
3.3 Individuals’ Access to PHI

HIPAA allows individuals to access and amend the protected health information collected about them and requires accounting for disclosures of PHI upon an individual's request. Such accountings can be done in a less detailed format where the individual is one of 50 or more study participants.

4. EXCEPTIONS TO HIPAA’S AUTHORIZATION REQUIREMENT

When health information is collected in the course of a study where health care, as discussed above, is provided, it is possible to use the health information for research purposes without individuals’ authorizations if the records are de-identified, are modified to constitute “limited data sets” (and used only pursuant to a Data Use Agreement), or are used and disclosed pursuant to an IRB waiver (only in exceptional cases).

4.1 Use or Disclosure of “De-Identified” Health Information

1) De-identified health information is exempt from HIPAA and may be used or disclosed for research purposes without an Informed Consent and Health Information Use and Disclosure Authorization.

2) Identifiers include the individual and the individual’s employer, relatives and household members that must be removed include: names; geographic subdivisions smaller than a state; zip codes; dates directly related to an individual; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images; and any other number, characteristic or code that could be used to identify the individual.

3) Re-identification Code. The de-identified information may be assigned a code that can be affixed to the research record that will permit the information to be re-identified if necessary, provided that, the key to such a code is not accessible to the researcher requesting to use or disclose the de-identified health information.

4) Researchers using de-identified data must certify that they have de-identified the data as described.

4.2 Limited Data Set

1) A researcher may use or disclose a Limited Data Set for any research purpose without an Informed Consent and Health Information Use and Disclosure Authorization.

2) A “Limited Data Set” is defined as PHI that may include any of the following direct identifiers:
   a) Town, city, State and zip code;
   b) All elements of dates directly related to an individual, including birth date, admission date, discharge date, and date of death.
3) A Limited Data Set must exclude all of the following direct identifiers of the individual or of the individual’s relatives, employers, or household members of the individual: names; postal address information other than town or city, State, and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other number, characteristic or code that could be used to identify the individual.

4) A Limited Data Set may be used or disclosed only if there is a Data Use Agreement between Northeastern University and the recipient of the limited data set.

5.0 WHAT RESEARCH REQUIRES REVIEW? 

If you are conducting research with human subjects, as defined below, your research requires review and approval for use of human subjects.

The Code of Federal Regulations [46.102f] defines a human subject as a living individual about whom an investigator obtains:

- data through intervention or interaction with the individual, (such as, interviews, surveys, clinical testing, or any other physical intervention or personal interaction), or
- identifiable private information.

Legal requirements to protect human subjects apply to a broader range of research than many investigators realize. Protections are required for research that uses:

- Bodily materials, such as cells, blood or urine, tissues, organs, hair or nail clippings, even if you did not collect these materials.
- Residual diagnostic specimens, including specimens obtained for routine patient care that would have been discarded if not used for research.
- Private information, such as medical information, which can be readily identified with individuals, even if the information was not specifically collected for the study in question. Research on cell lines or DNA samples that can be associated with individuals fall into this category.

These policies apply to research conducted by faculty, staff or students of Northeastern University, whether conducted on-campus or off-campus. Research that uses any NU property or non-public information to identify or contact prospective subjects must be reviewed and approved prior to recruiting participants or collecting data. Approval by NU is required in addition to approval from any other institution.
6.0 Procedures for Submitting Proposals for IRB Review

- Read the Policies and Procedures for Human Research Protections to understand the procedures for which you are responsible as an investigator and to assist you in completing the Application for Approval.

- Complete an Application for Approval for Use of Human Participants in Research.

This application and all other forms and instructions are found online at the HSRP website. You may copy the Application into a Word document and complete it in Word. You may also pick up all documents in the Office of Human Subject Research Protection, or call 617-373-7570 for forms to be mailed. Applications that are not completed in Word must be typed with each section designated by letter.

Directions for completing the Application for Approval are included in the application itself, in Application Instructions, and in additional references within the text. Using these references to complete your submission will hasten the approval process. Personnel at HSRP are available to assist researchers in answering questions on completing the application and about relevant regulations.

- A signed Assurance of the Principal Investigator must accompany each application. Other attachments, as described in the application, may be necessary.

- Only one copy of the Application for Approval and the appropriate attachments are necessary for the initial review submission.

7.0 Review Process

7.1 Initial Review

Upon receipt of the Request for Approval, the Office of Human Subject Research Protection (HSRP) conducts a preliminary review. Within 1 – 3 weeks after submitting their protocol, investigators can expect to be contacted with the results of this review. When necessary, investigators will be asked to provide additional information, clarification, or modifications. To prevent unnecessary delays, investigators are encouraged to follow the application instructions carefully on their initial submission and to provide any requested information as soon as possible. If follow-up communication is not received within 60 days, HSRP will request documentation of the status of the study and/or consider the application withdrawn. The IRB considers only specific and well-defined proposals; it does not give blanket authorization for broad or undefined topic areas.

As part of the initial review, HSRP assigns protocols to Exempt, Expedited Review or Full Committee Review status. The level of potential risk to the research participant determines the classification. Research categorized as Exempt or Expedited involves less than minimal risk or minimal risk, respectively, to the participant. Studies involving more than minimal risk require review by the full IRB. Final determination of Exempt, Expedited and Full Committee Status is made the IRB.
1. “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” 46.102(i)

7.2 For studies categorized as Exempt or Expedited [46.110]: 

Once the initial review is complete and the application is in satisfactory form, it is forwarded to the IRB chairperson for consideration of approval. If the Chair determines that the protocol can be approved as written, he will sign an approval. HSRP will send written notification of approval to the investigator. If a signed Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization is required from participants, HSRP will stamp the approved document. This stamped document is to be copied and provided to participants for signature. If the Chair has any concerns or requests, HSRP will contact the investigator to provide the necessary information or to make the modifications.

7.3 For projects requiring Full Committee Review [46.109]: 

The application will undergo initial review as described above. Once the proposal package is complete with any requested amendments or additions, HSRP will contact the investigator to set a date for review by the Institutional Review Board (IRB). The presence of the PI is requested at the meeting to discuss issues relevant to the protection of the research participants. Investigators are also requested to provide HSRP with sufficient copies of the protocol so IRB members may review the proposed research two weeks prior to the meeting. IRB meetings are held monthly and the meeting schedule is posted on the HSRP website. (NU IRB Meeting Schedule)

7.4 At the IRB meeting: 

The PI may present a very brief overview of the research. Committee members will use this opportunity to ask the PI questions to clarify or explain any issues that are unclear or about which they may have some concern. Members may discuss with the investigator procedures that will promote protection for the confidentiality or welfare of participants. The PI will then leave to allow private discussion by the members.

7.5 IRB Actions: 

Following discussion and resolution of any issues, the Board will take one of three actions:

- The Board may approve the proposal as written. If so, the PI will receive written notice of approval from HSRP.

- The Board may require the PI to amend the protocol or Informed Consent/Informed Consent and Health Information Use and Disclosure Authorization or provide additional information. If such materials are required, the Board will designate whether these amendments may be reviewed and approved by the IRB Chairperson, or reviewed by the full committee at the next scheduled meeting.

- The IRB also has the authority to disapprove research activities. The Board will provide written notification to the principal investigator of the decision. It will also include a statement of the
reasons for its decision and give the investigator an opportunity to respond in person or in writing.

All IRB actions should be communicated to the PI within one week of the meeting.

Approvals by IRB apply to use of human subjects only. University officials may require reviews and approvals for other reasons. However, no university official may approve research that has not been approved by the IRB. [cfr46.112]

7.6 Time Frame for Review

It is the investigator’s responsibility to allow sufficient time for the IRB approval process. Submission should be early if the researcher has deadlines for grant submissions, start dates for studies, etc. Protocols are reviewed in the order in which they are received.

Factors that affect the time frame necessary for review include:

- The completeness of the initial submission
- Review category, e.g., exempt status versus full committee review
- Number of protocols currently under active review by HSRP
- Response time by investigators to provide requested information or amendments
- Potential wait for IRB approvals or letters of permission from related sites

8.0 Student Research Proposals

Faculty advisors are considered the principal investigator for all student projects with human subjects. Advisors are therefore responsible that the research is conducted in accordance with federal regulations and university guidelines, including obtaining approvals. Prior to submission of a student protocol to HSRP, the advisor should review and approve the protocol and any necessary Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization, if applicable. A signed Assurance (original, not a copy) by the faculty advisor and the student must be submitted with the student’s proposal.

8.1 Classroom Research Involving Faculty and Students

Professors who assign a research project to be conducted by students within the time frame of an academic course should consult the Policy for Classroom Research Involving Faculty and Students and contact HSRP to discuss the project and obtain guidelines for review and approval of such research. This process should be initiated prior to the start of the course.

Arrangements can also be made with HSRP to have someone speak to students who will be conducting research about protection of human subjects in research and the submission and review process.

8.2 Using Students as Subjects

The faculty at Northeastern may not recruit students from their own classes for their personal research projects. Postings on general information boards may be used to recruit students.
9.0 Research Involving Children

Children are more vulnerable as research participants due to their limited capacity to understand and make responsible decisions concerning participation. Therefore, special caution is required in the preparation and review of protocols involving children as subjects [cfr46.401-409].

9.1 Obtaining parental permission/child assent

Written permission from the parent or guardian is required for a child to participate in research, including surveys and interviews, unless otherwise determined by HSRP.

A child cannot provide legal consent to participate in research. Provisions should be made by the PI to obtain assent from all children who are capable. Assent means a child’s affirmative agreement to be in the study. Failure to object is not considered assent. Children have the right to refuse to participate.

Assent is to be obtained from the child unless there is a clear, written justification for not obtaining assent, e.g., age, maturity, psychological state.

Assent may be oral if the PI provides sufficient explanation that written assent is not feasible.

Judgments about the capability of providing assent may be made for each child or for all the children. This must be clearly specified.

There must be a clear means of documenting how assent is obtained, and by whom. When appropriate, a separate assent form should be drafted with language appropriate to the child’s developmental level.

9.2 Explanation of and process for quitting or withdrawal from the research

Since children tend to be acquiescent to adult wishes and are often reluctant to speak up when uncomfortable, special attention must be given to processes for quitting or withdrawal from research. Along with the usual statements in the informed consent, the researcher is advised to:

Be cognizant of signs of discomfort shown by the child throughout the interview or testing procedures and periodically inquire about the child’s reactions or feelings.

Include procedures for withdrawal that address the above considerations.

HSRP makes the final determination of approved assent/permission procedures.

10.0 Other Vulnerable Populations

Individuals who are elderly, prisoners [cfr46.301-306], pregnant [cfr46.201-211], mentally-disabled, ill, economically or educationally-disadvantaged, do not speak English, etc., are likely to be vulnerable to coercion or undue influence and therefore require special precautions in research procedures [46.111(7b)]. Include additional safeguards in the protocol, consent, and Informed Consent and Health Information Use and Disclosure Authorization process to ensure that the rights and welfare of these participants are being protected adequately.
11.0 Diversity in Research

Investigators need to consider diversity in their recruitment strategies, as explained in this information from the Institutional Review Board Guidebook:

Applications “...that involve human subjects are required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy applies to all research involving human subjects and human materials, and applies to males and females of all ages. If one gender and/or minorities are excluded or are inadequately represented in this research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided. The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study.

12.0 Health Information Privacy Addressed by Informed Consent and Health Information Use and Disclosure Authorization

For research studies to which HIPAA applies (see Sec. 3.0), a new version of the informed consent form known as an Informed Consent and Health Information Use and Disclosure Authorization is now required.

Copies of signed Informed Consent and Health Information Use and Disclosure Authorization must be given to study participants for their records. (Sample Informed Consent and Health Information Use and Disclosure Authorization template).

Researchers can continue to rely upon authorizations signed by study participants prior to April 14, 2003. However, after April 14, 2003 all new authorizations to which HIPAA applies and which new study participants are signing must include the elements described above.

13.0 Continuing Review Procedures

For each approved study that has been reviewed under expedited or full committee status, Northeastern University’s Office of Human Subject Research Protection or the IRB assigns a continuing review interval and expiration date. The office sends notification to investigators 4-6 weeks prior to the impending expiration of the study approval. The investigator must complete the accompanying continuing review/study completion form (CRF) and return it at least two weeks before the designated date. The PI is required to complete the CRF whether the study is ongoing, has concluded or never started. Directions for completing the CRF are on the form.

If the study is ongoing or never started, the PI may request renewed approval. Studies that were originally approved under expedited procedures can be renewed by the same means.
received initial approval by the full committee must be reviewed at the next scheduled IRB meeting. The investigator must allow sufficient time for the review to be completed before the expiration date. If the study procedures have been followed as approved, the documentation is in order, and the IRB finds that there are no problems or new information that would change the approval status, the study will be renewed.

Projects that do not receive written notice of renewed approval from HSRP may not continue past the expiration date.

14.0 MODIFYING/CHANGING AN APPROVED PROTOCOL

After you have received written approval for your protocol and Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization, you must follow the procedures and use the informed consent or Informed Consent and Health Information Use and Disclosure Authorization as approved and on file at HSRP. However, if you need to make changes to the study, you may do so by requesting a modification in writing to HSRP [46.110 (b2)]. The modification must be approved before you institute the change.

Modifications that require approval include, but are not limited to, changes in PI, inclusion/exclusion criteria for subjects, sites of study, recruitment strategy, consent and authorization process, informed consent or Informed Consent and Health Information Use and Disclosure Authorization form, questions on survey/interview/focus groups, testing procedures, confidentiality measures, or safeguards for participants. Conducting a study with unapproved procedures invalidates the approval status.

To request approval for a change, address a memo to HSRP that states:

**Request for Modification**

1. PI name and contact person
2. Date
3. Project title and IRB #
4. Describe the requested modification and the reason for the change
5. State whether this change affects the level of risk to the participant
6. If the level of risk is increased, explain the extent of the risk and what procedures will be instituted to minimize it. Explain whether the risk affects current or only future subjects. Make appropriate changes to the consent document. The new consent must be approved as well.

Minimal changes are approved by expedited means and involve little time. Most changes fall in this category. If modifications are significant, they will be reviewed by the full IRB.
15.0 Adverse Events

Any adverse events involving human subjects must be promptly reported in writing to the Office of Human Subject Research Protection [cfr46.103(b5)]. Reporting must be made to Northeastern in addition to other sites that may be involved.

16.0 On Site Monitoring

In order to monitor whether research is carried out as approved, federal regulations [cfr46.109e] authorize Northeastern University to observe human subjects-related research procedures and the process of obtaining informed consent, and to conduct audits of research records and ensure that confidentiality is being maintained according to stated procedures.

Audits may also be conducted by agencies and sponsors such as the Office for Human Research Protections, the National Institutes of Health, and the Food and Drug Administration, etc.

Audits may be unannounced, so records should be readily available.

17.0 Suspension or Termination of IRB Approval

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 unexpected serious harm to subjects [46.113].

Investigators whose research does not comply with university policies may not obtain HSRP review or approval for other 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.