



Northeastern University

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HSRP Policies and Guidelines

Office of Human Subject Research Protection

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June 25, 2010

# Policies & procedures for human research protections

Office of Human Subject Research Protection, Northeastern University

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## Recommended Citation

Office of Human Subject Research Protection, Northeastern University, "Policies & procedures for human research protections" (2010). *HSRP Policies and Guidelines*. Paper 7. <http://hdl.handle.net/2047/d20003889>

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## **POLICIES & PROCEDURES FOR HUMAN RESEARCH PROTECTIONS**

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October 16, 2008

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## 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* <<http://ohsr.od.nih.gov/guidelines/belmont.html>> and are codified as regulations in *Title 45 Code of Federal Regulations Part 46* [1991] <<http://ohsr.od.nih.gov/guidelines/45cfr46.html>>. Investigators are strongly encouraged to read these and other relevant documents available at the National Institutes of Health Office of Human Subjects Research Regulations and Ethical Guidelines web site: <http://ohsr.od.nih.gov/guidelines/guidelines.html>. References to the Federal Code in this document are designated as [cfr46.101-409].

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.

## **4.0 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. See Appendix J for the De-Identification of Health Information Certification form.

## 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. See Appendix K for the approved Data Use Agreement.

## 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 [NU 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 (Appendix E). 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<sup>1</sup> 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.

### **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 Public Health Service:

"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-base 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."

Public Health Service, Application for Public Health Service Grants Guidebook

### **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. A sample Informed Consent and Health Information Use and Disclosure Authorization template can be found at Appendix D, Template 2.

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**



A continuing review of research is required at intervals appropriate to the degree of risk, but not less than once per year. [cfr46.109(e)]

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. Studies that 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 REQUESTING CHANGES TO THE APPROVED PROTOCOL OR INFORMED CONSENT AND HEALTH INFORMATION USE AND DISCLOSURE AUTHORIZATION**

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.



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Regulations require that HSRP report violations of university policies or federal regulations to the appropriate officials.



## APPLICATION INSTRUCTIONS

All the questions on the [Application for Approval](#) require a response. If you think a particular question does not apply, write N/A. No response areas should be blank. If you are unsure about what is necessary or if you have questions about your submission, please call 617-373-7570 for assistance.

**Please carefully edit and proof read before submitting the application. Applications that are not filled out completely and/or have any missing or incorrect information will be returned to the Principal Investigator.**

For additional assistance on:

1. Research with human specimens, see [NU IRB Policies & Procedures, Appendix G](#)
2. Secondary analysis of data, see [NU IRB Policies & Procedures, Appendix H](#)
3. NU administrative surveys, see [NU IRB Policies & Procedures, Appendix I](#)

### A. Investigator Information

**The Principal Investigator** is the person who has primary responsibility for the conduct of the study. If it is student research, the PI is the faculty advisor. If the study is funded, the PI is the grantee. If this is a subcontract to NU, the PI is the person who holds the subcontract at NU.

Circle whether PI is faculty, staff or “other”, describe “other” (e.g., faculty at BU), and provide the appropriate contact information.

**Indicate if this is student research.** Provide local, or current, contact information and student status.

**The contact person** is the person who will manage the application process with [Northeastern’s Office of Human Subject Research Protection \(HSRP\)](#). This may or may not be a person identified above. Indicate the person’s name. Add telephone and address only if not provided above.

### B. Protocol Information

**The title** used on this form must be identical to the title used on grant submissions, dissertations, site approvals, etc. for the same study. If your project title involves special circumstances, such as multiple funding sources for similar research or various phases of one project that will occur over time, please call this office to clarify title issues in advance.

**Give the total number of subjects** your project will participate in the project. If there are different aspects to the project, you may break it down, e.g., Total = 50 (Surveys = 40 Interviews =10)



**Give the dates that you anticipate beginning and ending the project.** If the study is funded, use the funding dates. Otherwise, use the dates you intend to begin recruitment and complete data analysis.

**Identify current or projected funding sources.** If there will be no funding, write “None.”

Identify whether this project has been submitted through:

NU’s Office of Research Administration and Finance (RAF)

Provost’s Office

NU Corporations and Foundations

### **C. Participants**

The federal government requires researchers to institute special precautions to protect individuals that may be “vulnerable” as research participants. These individuals may have a diminished capacity to make informed decisions regarding their participation, or they may be more vulnerable to coercion due to their circumstances (e.g., prisoners) or to their relationship to the investigator. Identify any potentially vulnerable populations in your study. In your protocol, consider additional safeguards that may be necessary when recruiting, obtaining informed consent, or conducting other study procedures.

*See also Code of Federal Regulations\* 46.201-211(pregnant women, fetuses); 46.301-306 (Prisoners); 46.401-409 (Children)*

Identify whether the project involves blood removal, investigational new drugs or devices, or videotapes/audiotapes.

### **D. Goals**

Briefly state the goals of this research in non-technical language.

### **E. Summary**

Briefly summarize the participants and procedures involved in this research in non-technical language.

### **F. Identify study personnel**

Key personnel include all investigators and those who will be involved in interacting with study participants or with handling data collected from participants. Indicate the function of the individual either here or in the text below. If the position has been created, but the person is not yet identified, describe the required qualifications or training the person will receive, as applicable.

#### **Examples:**

- *Sam Frank and Joyce Williams, NU graduate students in Psychology, will conduct the interviews.*



- *An undergraduate will be hired to enter the data and will be trained in the described procedures to maintain confidentiality.*
- *A person certified to perform venipuncture will do the blood draws.*

## **G. Other Institutions**

Identify other sites involved in this research. **For example,**

- schools, organizations, institutions where you plan to recruit and/or conduct the research
- institutions that may provide data or specimens
- sites that will conduct other aspects of this study; subcontracts
- institutions that hold the primary grant for which yours is a subcontract
- other offices, people, organizations that may provide information or other service, e.g., International Student Office, Lane Health Center
- other investigators, not named above, who may be conducting some study procedures off site

In many cases, current Institutional Review Board approval, written permission from the site, or other documentation of approval will be required.

## **H. Recruitment**

Issues that investigators need to consider with recruitment are 1) maintaining fairness in selection, and 2) preventing even the appearance of coercion. Populations should not be singled out solely because they may be “easier” to recruit (for example, institutionalized persons), if the PI intends to generalize results to a wider population. If certain people are targeted for participation, state why. If groups are excluded, state why. **For example,**

Only women will be surveyed because we want to learn how women perceive the barriers to advancement in this male-dominated field.

Care must be taken to prevent even the appearance of coercion in recruiting. Coercion is a factor if the participant perceives that s/he may suffer negative consequences for not participating. For example, an individual may feel s/he must participate if the researcher is in an authority position, such as teacher/student, care provider/patient, employer/employee, etc. relationships. This recruitment is discouraged but may be permitted if appropriate safeguards are in place. At Northeastern, instructors may not recruit their own students to be in their personal research. Posted ads may be used.

## **I. Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization Process**

Obtaining consent is a process, not merely having the person read a statement and sign it. The purpose is to ensure that the potential participant has complete understanding of the study and his/her role in it before agreeing to participate. It is the responsibility of the PI to ensure that the information is presented in a manner that each person can comprehend, that the person understands the risks and benefits, and has the opportunity to ask



questions. The PI must also make it completely clear that the potential participant is free to either participate or not without any negative consequences, and may quit at any time.

For populations who may be decisionally impaired, the PI must describe the conditions and procedures for obtaining appropriate consent. In some cases, (e.g., the mentally ill or aged), a determination must be made whether the person is capable or not. The procedures for this determination must be described. If it is determined that a parent, guardian, or other advocate must provide written consent, describe how this will be obtained. The participant must also provide consent/assent, if able, in addition to other consents. If this is not possible, explain why.

The consent process and the Informed Consent and Informed Consent and Health Information Use and Disclosure Authorization forms are critically important for the protection of participants in research. Obviously, the risk involved for the participant will determine the appropriate consent process.

For studies that qualify for exemption (see *Policies\**, Appendix E), a signed consent may not be required. Note that where individually identifiable health information is to be collected about any study participant, a signed Informed Consent and Health Information Use and Disclosure Authorization is required.

*For more information, refer to the Policies\*, section 7.0 Children; Appendix D Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization; the Code of Federal Regulations\* 46.116, 46.117 and 46.201-211 (pregnant women, fetuses); 46.301-306 (Prisoners); 46.401-409 (Children). HSRP/IRB makes the final determination for appropriate consent.*

## **J. Study Procedures**

All research procedures must be clearly described. If equipment or tests require explanation for a lay person, please do so. If applicable, differentiate activities/procedures/treatments that are research-related from program activities/procedures/treatments that the participant may already be engaged in. This distinction must be very clear in both your protocol and in the informed consent.

***For example:*** *A person is involved in a physical therapy program for treatment of an injury. The researcher wants to test the reliability of various pain measures by asking the person to evaluate his pain using these instruments. In the protocol and consent, clearly indicate that the only experimental portions to be considered are related to testing the pain measures, not the physical therapy procedures.*

## **K. Risks**

Study risks are not limited to physical harm. Consider any possible negative consequences to the individual for participating in your research. When identifying the risks, consider the magnitude of the risk as well as the likelihood that it may occur.



Provide information from published literature when possible and appropriate. State the precautions that you will take to minimize the risk, and procedures that you will follow if harm occurs.

**For example:**

*In similar studies, a few participants have become mildly upset during the interview when discussing the trauma they witnessed. The interviewer is experienced in counseling trauma victims and will stop the interview and provide immediate support. If the anxiety persists, the following actions will be taken....*

*There is a very small possibility of heart attack during the strenuous exercise in this program. However, it is very unlikely because the participants are healthy, athletic and <35 years old. Monitoring procedures conducted throughout the exercise include....*

*In case of emergency, these personnel and equipment are available..... and these procedures will be followed....*

## **L. Confidentiality**

Depending upon the nature of the information the researcher collects; loss of confidentiality can be a serious research risk for the participant. The level of risk assumed by the participant if the information were to be known by others determines the level of safeguards that the PI should institute to protect the participants. **For example:**

A survey or interview about individuals' illegal activities or their opinion of their job/employer has more potential for negative consequences for the participant if the information became known than a survey or interview on frequency of exercise or study habits.

Consider using the least identification possible starting with anonymity, then coding, and eliminating collection of unnecessary demographics and data. Destroy identifiable data or links to identifiers as soon as possible. Limit the number of people with access to identifiable, confidential data.

Videotapes and audiotapes are considered identifiable information. The limits of their use must be clear. If information is sensitive, transcription/analysis should be completed and the tapes destroyed as soon as feasible. If they are to be retained, state why.

All staff working with confidential data must be educated regarding appropriate protection of information.

## **M. Individual's Access to PHI**

For studies to which HIPAA applies, describe the process that will be used for allowing individuals to access their protected health information ("PHI") or, alternatively, advising them that they must wait until the end of the study to review their PHI. Individuals have the right to review and request amendment of their PHI records. However, the investigator can delay access to the PHI records until the end of the study if, for example, access would violate a double blind protocol or be disallowed by the protocol for



scientific reasons. The investigator must first have advised prospective participants of the possibility of such a delay within the Informed Consent and Health Information Use and Disclosure Authorization.



**N. Business Associates & Business Associate Agreements**

A “business associate” is a third-party organization or individual that performs a function or activity involving the use or disclosure of PHI obtained from research investigators. PHI provided to a business associate must be pursuant to written assurance that the business associate, and its sub-contractors, will use the information only for the purpose(s) intended, will restrict access to the information on a “need to know” basis only, and will otherwise take appropriate measures to safeguard the information in its possession. There must be a valid, signed Business Associate Agreement in place before identifiable health information may be provided. Please refer any questions about Business Associate Agreements to the Director of Research Integrity.

**O. Benefits**

Benefits to the individual or to society should be reasonable in proportion to the risk. A benefit is a positive outcome that a participant can reasonably expect from his/her involvement in the research procedures. Payment for participation is not considered a benefit.

**P. Attachments**

Include all relevant attachments.

*\*Policies and Procedures for Human Research Protections and the Code of Federal Regulations may be found at:*

[http://www.research.neu.edu/facts\\_rates\\_forms\\_policies/policies/documents/humansubjectspolicymanual.pdf](http://www.research.neu.edu/facts_rates_forms_policies/policies/documents/humansubjectspolicymanual.pdf) and <http://ohsr.od.nih.gov/guidelines/45cfr46.html>, respectively.



For NU IRB use:

Date Received: \_\_\_\_\_ NU IRB No. \_\_\_\_\_

Review Category: \_\_\_\_\_ Approval Date \_\_\_\_\_

APPLICATION FOR APPROVAL FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

Before completing this application, please read the [Application Instructions](#) and [Policies and Procedures for Human Research Protections](#) to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. The document, *Application Instructions*, provides additional assistance in preparing this submission. **Incomplete applications will be returned to the investigator. You may complete this application online and save it as a Word document.**

*If this research is related to a grant, contract proposal or dissertation, a copy of the full grant/contract proposal/dissertation must accompany this application.*

**Please carefully edit and proof read before submitting the application. Applications that are not filled out completely and/or have any missing or incorrect information will be returned to the Principal Investigator.**

REQUIRED TRAINING FOR RESEARCH INVOLVING HUMAN SUBJECTS

Under the direction of the [Office of the Vice Provost for Research](#), Northeastern University is now requiring 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>. **This requirement will be effective as of November 15, 2008 for all new protocols.**

**Principal Investigators, student researchers and key personnel (participants who contribute substantively to the scientific development or execution of a project) must include a copy of their certificate of completion for this web-based tutorial with the protocol submission.**

- Certificate(s) Attached
- Certificate(s) submitted previously – on file with the NU's Office of Human Subject Research Protection

**A. Investigator Information**

Principal Investigator (**PI cannot be a student**) \_\_\_\_\_

Investigator is: NU Faculty\_\_\_ NU Staff\_\_\_ Other \_\_\_\_\_

College \_\_\_\_\_

Department \_\_\_\_\_

Address \_\_\_\_\_



Telephone \_\_\_\_\_ Email \_\_\_\_\_

**Is this student research?** YES \_\_\_ NO \_\_\_ If yes, please provide the following information:

Student Name \_\_\_\_\_ Undergrad \_\_\_ MA/MS \_\_\_ PhD \_\_\_

Mailing Address \_\_\_\_\_ Anticipated graduation date \_\_\_\_\_

Telephone \_\_\_\_\_ Primary Email \_\_\_\_\_

Cell phone \_\_\_\_\_ Secondary Email \_\_\_\_\_

**B. Protocol Information**

Title \_\_\_\_\_

Projected # subjects \_\_\_\_\_

Approx. begin date of project \_\_\_\_\_ month, day, year      Approx. end date \_\_\_\_\_ month, day, year

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).

- Anticipated funding source for project (or none) \_\_\_\_\_
- Has/will this proposal been/be submitted through:
  - NU's Office of Research Administration and Finance (RAF) \_\_\_\_\_
  - Provost \_\_\_\_\_
  - Corp & Foundations \_\_\_\_\_

**C.**

<b>Will Participants Be:</b>	<b>Yes</b>	<b>No</b>	<b>Does the Project Involve:</b>	<b>Yes</b>	<b>No</b>
Children (<18)	_____	_____	Blood Removal?	_____	_____
Northeastern University Students?	_____	_____	Investigational drug/device?	_____	_____
Institutionalized persons?	_____	_____	Audiotapes/videotapes?	_____	_____
Prisoners?	_____	_____			
Cognitively Impaired Persons?	_____	_____			
Non or Limited English Speaking Persons?	_____	_____			
People Living outside the USA?	_____	_____			
Pregnant Women/Fetuses?	_____	_____			
Other? (Please provide detail)	_____	_____			



***Please answer each of the following questions using non-technical language. Missing or incomplete answers will delay your review while we request the information.***

**D. What are the goals of this research? Please state your research question(s) and related hypotheses.**

**E. Provide a brief summary of the purpose of the research in non-technical language.**

**F. Identify study personnel on this project. Include name, credentials, role, and organization affiliation.**

**G. Identify other organizations or institutions that are involved. Attach current Institutional Review Board (IRB) approvals or letters of permission as necessary.**



## **H. Recruitment Procedures**

Describe the participants you intend to recruit. Provide all inclusion and exclusion criteria. Include age range, number of subjects, gender, ethnicity/race, socio-economic level, literacy level and health (as applicable) and reasons for exempting any groups. Describe how/when/by whom inclusion/exclusion criteria will be determined.

Describe the procedures that you will use to recruit these participants. Be specific. How will potential subjects be identified? Who will ask for participation? If you intend to recruit using letters, posters, fliers, ads, website, email etc., copies must be included as attachments for stamped approval. Include scripts for intended telephone recruitment.

What remuneration, if any, is offered?



## I. Consent Process

Describe the process of obtaining informed consent\*. Be specific. How will the project and the participants' role be presented to potential participants? By whom? When? Where? Having the participant read and sign a consent statement is done only after the researcher provides a detailed oral explanation and answers all questions. Please attach a copy of informed consent statements that you intend to use, if applicable.

If your study population includes non-English speaking people, translations of consent information are necessary. Describe how information will be translated and by whom. You may wait until the consent is approved in English before having it translated.

If your population includes children, prisoners, people with limited mental capacity, language barriers, problems with reading or understanding, or other issues that may make them vulnerable or limit their ability to understand and provide consent, describe special procedures that you will institute to obtain consent appropriately. If participants are potentially decisionally impaired, how will you determine competency?

\*If incomplete disclosure during the initial consent process is essential to carrying out the proposed research, please provide a detailed description of the debriefing process. Be specific. When will full disclosure of the research goals be presented to subjects (e.g., immediately after the subject has completed the research task(s) or held off until the completion of the study's data collection)? By whom? Please attach a copy of the written debriefing statement that will be given to subjects.

## J. Study Procedures

Provide a detailed description of all activities the participant will be asked to do and what will be done to the participants. Include the location, number of sessions, time for each session, and total time period anticipated for each participant, including long term follow up.

Who will conduct the experimental procedures, questionnaires, etc? Where will this be done? *Attach copies of all questionnaires, interview questions, tests, survey instruments, links to online surveys, etc.*



### **K. Risks**

Identify possible risks to the participant as a result of the research. Consider possible psychological harm, loss of confidentiality, financial, social, or legal damages as well as physical risks. What is the seriousness of these risks and what is the likelihood that they may occur?

Describe in detail the safeguards that will be implemented to minimize risks. What follow-up procedures are in place if harm occurs? What special precautions will be instituted for vulnerable populations?

### **L. Confidentiality**

Describe *in detail* the procedures that will be used to maintain anonymity or confidentiality during collection and entry of data. Who will have access to data? How will the data be used, now and in the future?

How and where will data be stored? When will data, including audiotapes and videotapes, be destroyed? If data is to be retained, explain why. Will identifiers or links to identification be destroyed? When? Signed consent documents must be retained for 3 years following the end of the study. Where and how will they be maintained?

### **M. If your research is HIPAA-protected, please complete the following; Individual Access to PHI**

Describe the procedure that will be used for allowing individuals to access their PHI or, alternatively, advising them that they must wait until the end of the study to review their PHI.

### **N. Benefits**

What benefits can the participant reasonably expect from his/her involvement in the research? If none, state that. What are potential benefits to others?



**O. Attachments**

**Identify attachments that have been included and those that are not applicable (n/a).**

- \_\_\_\_\_ Copy of fliers, ads, posters, emails, web pages, letters for recruitment \*
- \_\_\_\_\_ Scripts of intended telephone conversations\*
- \_\_\_\_\_ Copies of IRB approvals or letters of permission from other sites
- \_\_\_\_\_ [Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization](#)\*
- \_\_\_\_\_ Debriefing Statement\*
- \_\_\_\_\_ Copies of all instruments, surveys, focus group or interview questions, tests, etc.
- \_\_\_\_\_ [Signed Assurance of Principal Investigator Form](#) (required)
- \_\_\_\_\_ NIH Human Subject Training Certificate(s) (required if not already on file at HSRP)

*\* (Approved forms must be stamped by the IRB before use)*

**P. Health Care Provision During Study**

Please check the applicable line:

- \_\_\_\_\_ I have read the description of HIPAA “health care” within [Section 3.0 of the Policies & Procedures for Human Research Protection](#). I am not a HIPAA-covered health care provider and no health care will be provided in connection with this study.
- \_\_\_\_\_ I am a HIPAA-covered health care provider or I will provide health care in connection with this study as described in [Section 3.0 of the Policies & Procedures for Human Research Protection](#). This health care is described above under “Study Procedures,” and the Informed Consent and Health Information Use and Disclosure Authorization form will be used with all prospective study participants.

If you have any questions about whether you are a HIPAA-covered health care provider, please contact Nan C. Regina, Director, [Human Subject Research Protection](#) at [n.regina@neu.edu](mailto:n.regina@neu.edu) or (617) 373-4588.

**Please return the completed application to:**

Nan C. Regina, Director  
Human Subject Research Protection  
960 Renaissance Park  
Northeastern University  
Boston, MA 02115-5000  
Tel: 617.373.7570; Fax: 617.373.4595  
[n.regina@neu.edu](mailto:n.regina@neu.edu)

*The application and accompanying materials may be sent as [email attachments](#) or in hard copy. A signed [Assurance of Principal Investigator Form](#) may be sent via fax or in hard copy.*



Appendix C

**ASSURANCE OF PRINCIPAL INVESTIGATOR FORM**

**Northeastern University  
Institutional Review Board**

**ASSURANCE OF PRINCIPAL INVESTIGATOR**

Investigator(s): \_\_\_\_\_

Title of Proposal: \_\_\_\_\_

**To give assurance, please read and initial each statement, then sign below.**

- \_\_\_\_\_ 1. I have read and understand Northeastern University's *Policies and Procedures Concerning the Protection of Human Subjects* and the *Federal Wide Assurance*. I give my assurance that I, and all members of the research team, will adhere to the policies in this research.
- \_\_\_\_\_ 2. I assure that no participants will be recruited or enrolled, and no data will be collected, without current, written approval from Northeastern University, and other sites as required.
- \_\_\_\_\_ 3. I assure that the rights and welfare of all participants will be protected according to the procedures approved for this project by the NU IRB.
- \_\_\_\_\_ 4. I assure that all risks or discomforts to subjects will be clearly explained, and that I will demonstrate how risks are outweighed by potential benefits to the subject or by the importance of the knowledge to be gained.
- \_\_\_\_\_ 5. I assure that the informed consent of all participants will be obtained by methods that meet the requirements of Northeastern University's policy and assurance procedures.
- \_\_\_\_\_ 6. I assure that no changes in research activity will be initiated without prior NU IRB review and approval, except where necessary to eliminate apparent immediate hazard to the subjects.
- \_\_\_\_\_ 7. I assure that I will report any problems involving risks to human subjects or others **promptly** to the Office of Human Subject Research Protection.
- \_\_\_\_\_ 8. I assure that there are no financial or other relationships (e.g., stock ownership, advisory board, speaker's bureaus, honoraria) that might be viewed as creating a conflict of interest.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Principal Investigator / Faculty Advisor

For student research, the faculty advisor is the principal investigator for the study and is primarily responsible for the ethical conduct of the research. Faculty must review and approve student research prior to submission for NU IRB review. Student investigators must sign this Assurance also.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Student Investigator

**DEPARTMENT CHAIR/PROGRAM DIRECTOR SIGNATURE (*Required*)**  
**I am aware that this protocol is being submitted to the Northeastern University IRB. I do not make any assertions about human subject protections for this research project.**  
Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
**Department Chair or Program Director**

Please return completed form to: **Human Subject Research Protection**  
**960 Renaissance Park - Northeastern University**  
**Boston, MA 02115**  
**Tel: 617.373.7570; Fax: 617.373.4595**



## **APPENDIX D - THE INFORMED CONSENT OR INFORMED CONSENT AND HEALTH INFORMATION USE AND DISCLOSURE AUTHORIZATION**

### **General Requirements** [cfr46.116 (a,b)]

- No investigator can involve a person in a research study without the legally effective informed consent of the participant or the participant's legally authorized representative, unless it has been determined otherwise by [Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#) in accordance with federal regulations.
- The investigator must obtain consent under circumstances that a) provide the potential participant or representative sufficient opportunity to consider participation and that b) minimize the possibility of coercion or undue influence.
- The information must be written in language that the person, or representative, can easily understand.
- The consent cannot include any language that waives or appears to waive any legal rights of the participant. It cannot include any language that releases the principal investigator, Northeastern University, a sponsoring agency or individuals from liability for negligence.

### **Writing the Consent Document**

To ensure that participants understand the nature of the research and their personal involvement, investigators must provide a thorough oral explanation to prospective subjects and answer their questions. For most research that qualifies for exempt, expedited or full committee review, investigators must also obtain a signed consent from participants. There are instances where the Federal regulations ([45 CFR 46.117c](#)) allow an IRB to waive the requirement for the investigator to obtain a signed consent form. [You may use the formats provided on our website](#) or you may alter the format if the information conforms to guidelines.

The nature of your research and the level of risk determine the type and amount of information that you need to include. Consider what the person will need to know in order to make an informed decision to participate. For example, interviews or questionnaires with highly sensitive questions require detailed information about procedures to protect confidentiality. Research involving therapy or exercise may need more information about physical risks.

Each section is not required for every consent. Sections marked \* are required unless otherwise determined by HSRP. You may also combine sections if that is a better way to present the information. For some research, additional information may be required. Check the listing following the signatures on the consent template.

Examples of wording are occasionally provided. Use this wording only if it applies exactly to the procedures you will be following. Otherwise, make appropriate modifications.

**Consent documents should be written at an 8<sup>th</sup> grade reading level or less** for the average adult population. Avoid technical or professional language used in grant submissions or with peers. Use short, clear sentences. Use bullets or timetables for multiple visits or procedures. Select an easy-to-read font size. Use second person (you) statements rather than first person. Use correct spelling and grammar. If the consent is more than one page, use footers: page 1 of 3, page 2 of 3, etc.



If some or all participants may not understand 8<sup>th</sup> grade English (e.g., children, non-English speakers, cognitively impaired persons), appropriate accommodations must be made to obtain consent.

Microsoft Word offers a useful tool to help you determine if your consent form is at an 8th grade reading level. To display readability statistics do the following:

1. On the **Tools** menu, click **Options**, and then click the **Spelling & Grammar** tab.
2. In the Grammar section, select the **Check grammar with spelling** check box and the **Show readability statistics** check box
3. Then click **OK**.
4. Open your consent document and now run the “Spelling and Grammar” check function on the Standard Toolbar 

When Microsoft Word finishes checking spelling and grammar, it will display information about the reading level of the document using the Flesch-Kincaid Reading Ease score, which rates texts on a U.S. grade-school level.

**TIP:** To lower the grade level, consider using shorter words and shorter sentences.

**For children** (<age 18 in MA) to participate in research, including surveys and interviews, signed permission is required from the parent or legal guardian and a signed assent from the child, unless otherwise approved by HSRP. See *Policies* section 7.0.

**Translations** of consent information are necessary for non-English speaking people. Describe how information will be translated and by whom. You may wait until the consent approved in English before having it translated.

**For a decisionally impaired person**, a legally authorized representative (LAR) must provide written permission. Provide signature and date spaces for the LAR and the participant, if the latter is capable of consent.

**State whether the subjects and data are anonymous or confidential.** If subjects are anonymous, no one, *including the researcher*, knows the identity of those who participated in the study or which data they provided. If the information is confidential, the identity of participants and the data is known, but is kept in strict confidence within legal limits. Coding identities and storing data in locked files are methods of preventing private information about subjects from being revealed.

Once the informed consent or **Informed Consent and Health Information Use and Disclosure Authorization** has been approved in its final form, HSRP will stamp it and include the IRB tracking number and the dates the consent is valid. **Copies of this original stamped version MUST be used to recruit participants.** No changes to the authorization are permitted without prior approval and a new authorized version by HSRP.

**A copy of the consent must be given to every participant.** The PI retains the original signed statement. The investigator must retain these documents for at least three years past the completion of the research activity.

**In case of audit**, the investigator will be required to provide documentation that appropriate signed and dated consent was obtained by each participant on the approved consent document.



▪ **Template 1    Format for Signed Informed Consent Document**

.....

**Northeastern University, Department**  
**Investigator Name**  
**Title of Project**

**Informed Consent to Participate in a Research Study**

We are inviting you [or your child] to take part in a research study. This form will tell you about the study, but the researcher will explain it to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, the researcher will ask you to sign this statement and will give you a copy to keep.

**Why am I being asked to take part in this research study?**

Explain if the person is being recruited because of special or clinical characteristics.

**Ex:** *We are asking you to be in this study because you are a Gulf War veteran.*

**Why is this research study being done?**

State the purpose of the study in lay language.

**Ex:** *The purpose of this research is to develop a survey that will be useful in measuring whether people with arthritis are doing better or worse after treatment.*

**Is preferable to:**

*The purpose of this research is to develop a psychometrically valid and reliable instrument that will provide quantitative data that can be analyzed to support treatment and management decisions for people with arthritis.*

**What will I be asked to do?**

If you decide to take part in this study, we will ask you to \_\_\_\_\_.

Describe all the tasks that the person will be asked to do, or describe what will be done to them. Provide sufficient detail so the person understands what his/her role entails. If it involves questionnaires, provide a brief description. If it involves unfamiliar equipment, explain how it will be used. Use lay language rather than technical/professional terms. Use bullets or timetables for research that has multiple visits or tasks.

Identify and describe any procedures that are experimental.

If applicable, differentiate between research procedures and routine procedures. For example, if you wish to add a research component to a regularly scheduled (non-research) program, clearly identify the tasks that are program-related and those that are research-related. Be clear that the person may continue with the regular program even if they decide not to participate in the research component.

If the study is randomized, explain randomization.



### **Where will this take place and how much of my time will it take?**

Tell the person where each part of the study will be conducted and how long each part will take.

**Ex:** *You will be interviewed in your own home or at a time and place that is convenient for you. The interview will take about one hour. Three months later, we will mail you a follow-up questionnaire with 25 questions that will take 20- 30 minutes to complete. You can mail it back to us in the stamped envelope we will provide.*

### **Will there be any risk or discomfort to me?**

Identify any reasonable foreseeable risks, harms, discomforts or inconvenience that the participant may experience. Indicate the likelihood that it may occur as well as the seriousness. Consider legal, financial, social, psychological, physical, etc. risks. Describe the precautions you will take to minimize the risks, discomforts or inconvenience. Describe follow up for any adverse event (anxiety, physical injury). If there is no foreseeable risk or discomfort, state that.

### **Will I benefit by being in this research?**

Describe any personal benefits that the participant may reasonably expect from their participation. If there is no direct benefit, state that. Payment for participation is not considered a benefit.

**Ex:** *There will be no direct benefit to you for taking part in the study. You may add, "However, the information learned from this study may help ...."*

### **Who will see the information about me?**

If the participant's identity **WILL NOT** be matched to their responses:

**Ex:** *Your identity as a participant in this study will not be known. That means no one, not even the researchers, will know that the answers you give are from you.*

If the participant's identity **WILL** be matched to their responses:

Explain who will have access to information and in what form.

**Ex:** *Your part in this study will be confidential. Only the researchers on this study will see the information about you. No reports or publications will use information that can identify you in any way.*

Describe the procedures you will use to protect personal information. If codes are used, describe coding procedures. Explain how data will be maintained, and when/if data will be destroyed. Audiotapes and videotapes are considered identifiable information, even if no names are included.

Describe any limits to confidentiality. For example, identify any legal reporting requirements, e.g., child abuse. Specify what information must be reported, under what circumstances, and to whom. Also, explain official oversight or monitoring that may be done by NU, government agencies, sponsors, etc.

**Ex:** *In rare instances, authorized people may request to see research information about you and other people in this study. This is done only to be sure that the research is done*



properly. We would only permit people who are authorized by organizations such as Northeastern University or [FDA, OHRP, sponsor] to see this information.

**If I do not want to take part in the study, what choices do I have?**

For treatment studies, alternatives to participation must be identified and described. For example, if the person does not want to participate in an experimental physical therapy program, inform the person about standard physical therapy or other appropriate health care.

If your study does not involve treatment or other potential benefit, the participant's option is to not participate. In that case, you may omit this section.

**What will happen if I suffer any harm from this research?**

If research-related injury (i.e. physical, psychological, social, financial or otherwise) is possible in research, provide an explanation of whatever compensation or treatment will be provided. If physical injury is possible, explain whether any medical treatment is available, what it consists of, and where further information may be obtained.

When appropriate, you may use wording such as, *No special arrangements will be made for compensation or for payment for treatment solely because of my participation in this research.*

**Can I stop my participation in this study?**

*Ex: Your participation in this research is completely voluntary. You do not have to participate if you do not want to. Even if you begin the study, you may quit at any time. If you do not participate or if you decide to quit, you will not lose any rights, benefits, or services that you would otherwise have [as a student, employee, etc].*

**Who can I contact if I have questions or problems?**

Include the name and viable contact information of one or more appropriate people. If there is a possibility of an emergency, be sure an immediate response is available.

**Who can I contact about my rights as a participant?**

*Ex: If you have any questions about your rights as a participant, you may contact Human Subject Research Protection, Division of Research Integrity, 960 Renaissance Park, Northeastern University Boston, MA 02115 tel. 617-373-7570, email: [irb@neu.edu](mailto:irb@neu.edu). You may call anonymously if you wish.*

**Will I be paid for my participation?**

If participants will be paid or given a gift, state what the payment is and when it will be given.

*Ex: You will be given a \$5 gift certificate to Chicken Lou's as soon as you complete the Nutritional Quality of Life Survey.*

**Will it cost me anything to participate?**

State any costs that may be incurred by the participant for the study, e.g., parking.



**Is there anything else I need to know?**

Include any pertinent information that may not be stated elsewhere.

For example:

*You must be at least 18 years old to participate unless your parent or guardian gives written permission.*

*This research is paid for by Boston Police Dept; XYZ Pharmaceuticals; Internal Revenue Service*

**I agree to [have my child] take part in this research.**

\_\_\_\_\_  
Signature of person [parent] agreeing to take part

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person above

\_\_\_\_\_  
Signature of person who explained the study to the participant above and obtained consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person above

**\*Required section unless otherwise determined by HSRP.**

**Depending upon the nature of your research, you are required to provide information about one or more of the following if it is applicable:**

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. a statement that significant new finding(s) developed during the course of the research which may be related to the subject's willingness to continue participation will be provided to the subject.
6. the approximate number of subjects involved in the study.



## **Template 2 Format for Signed Informed Consent and Health Information Use and Disclosure Authorization**

.....  
**Northeastern University, Department**  
**Investigator Name**  
**Title of Project**

### **Informed Consent and Health Information Use and Disclosure Authorization**

We are inviting you [or your child] to take part in a research study. This form will tell you about the study, but the researcher will explain it to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, the researcher will ask you to sign this statement and will give you a copy to keep.

#### **Why am I being asked to take part in this research study?**

Explain if the person is being recruited because of special or clinical characteristics.

**Ex:** *We are asking you to be in this study because you are a Gulf War veteran.*

#### **Why are you doing this research study and for what purpose will my health information be used and disclosed?**

State the purpose of the study in lay language.

**Ex:** *The purpose of this research is to develop a survey that will be useful in measuring whether people with arthritis are doing better or worse after treatment.*

#### **Is preferable to:**

*The purpose of this research is to develop a psychometrically valid and reliable instrument that will provide quantitative data that can be analyzed to support treatment and management decisions for people with arthritis.*

#### **Who will be using and disclosing information about me?**

State the persons or classes of persons, which will use and disclose health information.

**Ex:** *Department of Physical Therapy faculty, staff, and students will use and disclose your health information pursuant to this authorization.*

#### **What will I be asked to do?**

If you decide to take part in this study, we will ask you to \_\_\_\_\_.

Describe all the tasks that the person will be asked to do, or describe what will be done to them. Provide sufficient detail so the person understands what his/her role entails. If it involves questionnaires, provide a brief description. If it involves unfamiliar equipment, explain how it will be used. Use lay language rather than technical/professional terms. Use bullets or timetables for research that has multiple visits or tasks.

Identify and describe any procedures that are experimental.



If applicable, differentiate between research procedures and routine procedures. For example, if you wish to add a research component to a regularly scheduled (non-research) program, clearly identify the tasks that are program-related and those that are research-related. Be clear that the person may continue with the regular program even if they decide not to participate in the research component.

If the study is randomized, explain randomization.

**Where will this take place and how much of my time will it take?**

Tell the person where each part of the study will be conducted and how long each part will take.

*Ex: You will be interviewed in your own home or at a time and place that is convenient for you. The interview will take about one hour. Three months later, we will mail you a follow-up questionnaire with 25 questions that will take 20- 30 minutes to complete. You can mail it back to us in the stamped envelope we will provide.*

**Will there be any risk or discomfort to me?**

Identify any reasonable foreseeable risks, harms, discomforts or inconvenience that the participant may experience. Indicate the likelihood that it may occur as well as the seriousness. Consider legal, financial, social, psychological, physical, etc. risks. Describe the precautions you will take to minimize the risks, discomforts or inconvenience. Describe follow up for any adverse event (anxiety, physical injury). If there is no foreseeable risk or discomfort, state that.

**Will I benefit by being in this research?**

Describe any personal benefits that the participant may reasonably expect from their participation. If there is no direct benefit, state that. Payment for participation is not considered a benefit.

*Ex: There will be no direct benefit to you for taking part in the study. You may add, "However, the information learned from this study may help ...."*

**What health information will be used and disclosed?**

Describe in a definite way what information will be used and disclosed.

*Ex: All of the health information collected about me in the course of the study.*

**Who will see the information about me?**

If the participant's identity **WILL NOT** be matched to their responses:

*Ex: Your identity as a participant in this study will not be known. That means no one, not even the researchers, will know that the answers you give are from you.*

If the participant's identity **WILL** be matched to their responses:

Explain who will have access to information and in what form.

*Ex: Your part in this study will be confidential. Only the researchers on this study will see the information about you. No reports or publications will use information that can identify you in any way.*



Describe the procedures you will use to protect personal information. If codes are used, describe coding procedures. Explain how data will be maintained, and when/if data will be destroyed. Audiotapes and videotapes are considered identifiable information, even if no names are included.

Describe any limits to confidentiality. For example, identify any legal reporting requirements, e.g., child abuse. Specify what information must be reported, under what circumstances, and to whom. Also, explain official oversight or monitoring that may be done by NU, government agencies, sponsors, etc.

**Ex:** *In rare instances, authorized people may request to see research information about you and other people in this study. This is done only to be sure that the research is done properly. We would only permit people who are authorized by organizations such as Northeastern University or [FDA, OHRP, sponsor] to see this information.*

**Note: Some persons or organizations that receive your health information pursuant to this authorization may not be covered by the Health Insurance Portability and Accountability Act or other privacy laws.**

#### **If I do not want to take part in the study, what choices do I have?**

For treatment studies, alternatives to participation must be identified and described. For example, if the person does not want to participate in an experimental physical therapy program, inform the person about standard physical therapy or other appropriate health care.

If your study does not involve treatment or other potential benefit, the participant's option is to not participate. In that case, you may omit this section.

#### **What will happen if I suffer any harm from this research?**

If research-related injury (i.e. physical, psychological, social, financial or otherwise) is possible in research, provide an explanation of whatever compensation or treatment will be provided. If physical injury is possible, explain whether any medical treatment is available, what it consists of, and where further information may be obtained.

When appropriate, you may use wording such as, *No special arrangements will be made for compensation or for payment for treatment solely because of my participation in this research.*

#### **Can I stop my participation in this study?**

**Ex:** *Yes. Your participation in this research is completely voluntary. You do not have to participate if you do not want to. Even if you begin the study, you may quit at any time. Please send a written request for withdrawal to the Principal Investigator responsible for the study. If you do not participate or if you decide to quit, you will not lose any rights, benefits, or services that you would otherwise have [as a student, employee, etc]. However, the researcher can continue to use the health information collected about you prior to your withdrawing your authorization.*



**Who can I contact if I have questions or problems?**

Include the name and viable contact information of one or more appropriate people. If there is a possibility of an emergency, be sure an immediate response is available.

**Who can I contact about my rights as a participant?**

**Ex:** *If you have any questions about your rights as a participant, you may contact the Division of Research Integrity, 960 Renaissance Park, Northeastern University Boston, MA 02115 tel. 617-373-7570, email: [irb@neu.edu](mailto:irb@neu.edu). You may call anonymously if you wish.*

**Can I access the health information collected about me and request corrections where necessary?**

If the study is HIPAA-covered, individuals generally have a right to review and request amendment of their health records. However, an investigator can delay access to the PHI records until the end of the study if, for example, access would violate a double blind protocol or be disallowed by the protocol for scientific reasons. The investigator must first have advised the prospective participant of the possibility of such a delay within this Informed Consent and Health Information Use and Disclosure Authorization. The individual must be told to contact the principal investigator directly with requests for access to his or her PHI records.

**Will I be paid for my participation?**

If participants will be paid or given a gift, state what the payment is and when it will be given.

**Ex:** *You will be given a \$5 gift certificate to Chicken Lou's as soon as you complete the Nutritional Quality of Life Survey.*

**Will it cost me anything to participate?**

State any costs that may be incurred by the participant for the study, e.g., parking.

**Is there anything else I need to know?**

Include any pertinent information that may not be stated elsewhere.

For example:

*You must be at least 18 years old to participate unless your parent or guardian gives written permission.*

*This research is paid for by Boston Police Dept; XYZ Pharmaceuticals; Internal Revenue Service*

**If the study is HIPAA-covered, when will this authorization end?**

(Recommend that this date be indefinite)



**I agree to [have my child] take part in this research and authorize the use and disclosure of my health information consistent with provisions above.**

\_\_\_\_\_  
Signature of person [parent] agreeing to take part

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person above

\_\_\_\_\_  
Signature of person who explained the study to the participant above and obtained consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person above

**\*Required section unless otherwise determined by HSRP.**

**Depending upon the nature of your research, you are required to provide information about one or more of the following if it is applicable:**

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new finding(s) developed during the course of the research which may be related to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.



**TEMPLATE 3 UNSIGNED CONSENT DOCUMENT**

45 CFR 46 117(c) In certain instances, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.** When a signed informed consent is not required, this consent form may be given to participants to keep. Please modify the following information as necessary.

**Northeastern University, Department of:**

**Name of Investigator(s):** *[Principal Investigator's name, Student Researcher's name]*

**Title of Project:**

**Request to Participate in Research**

We would like to invite you to take part in a research project. The purpose of this research is to \_\_\_\_\_.

**You must be at least 18 years old** to be in this research project. *[Unless specifically approved otherwise by HSRP]*

The study will take place at \_\_\_\_\_ and will take about \_\_\_\_\_ *[minutes/hours/sessions/etc.]*. If you decide to take part in this study, we will ask you *[to fill out a survey/answer a series of questions/discuss your opinions/etc.]* about \_\_\_\_\_.

**There are no foreseeable risks or discomforts to you for taking part in this study.**

**OR**

**The possible risks or discomforts of the study are minimal.** You may feel a little *[uncomfortable/embarrassed/sad/tired/etc.]* answering *[personal/sensitive/many/etc.]* questions.

**There are no direct benefits to you for participating in the study.** However, your answers may help us to learn more about \_\_\_\_\_.

**Your part in this study is anonymous.** That means no one will know if you took part in this study and no one, including the researcher, will know what your answers are. Any reports or publications based on this research will use only group data and will not identify you or any individual as being of this project.

**OR**

**Your part in this study will be handled in a confidential manner.** Only the researchers will know that you participated in this study. Any reports or publications based on this research will use only group data and will not identify you or any individual as being of this project.

**The decision to participate in this research project is up to you.** You do not have to participate and you can refuse to answer any question. Even if you begin the study, you may withdraw at any time.

**You will not be paid for your participation in this study.**

**OR**

*[If participants will be paid or receive a gift, state what the payment is and when it will be given. For example: You will receive a \$5 gift certificate to Dunkin Donuts at the end of the focus group.]*

**If you have any questions about this study,** please feel free to call \_\_\_\_\_ *[name and contact information]*, the person mainly responsible for the research. You can also contact *[name and contact information]*, the Principal Investigator.

**If you have any questions about your rights in this research,** you may contact Human Subject Research Protection, Division of Research Integrity, 960 Renaissance Park, Northeastern University, Boston, MA 02115. Tel: 617.373.7570, Email: [irb@neu.edu](mailto:irb@neu.edu). You may call anonymously if you wish.

You may keep this form for yourself.

Thank you.



Name of Investigator

**TEMPLATE 4 UNSIGNED CONSENT DOCUMENT FOR WEB-BASED ONLINE SURVEYS**

[45 CFR 46 117\(c\)](#) In certain instances, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.**

*Please modify the following information as necessary.*

Northeastern University, Department of:

Name of Investigator(s): *[Principal Investigator's name, Student Researcher's name]*

Title of Project:

**Request to Participate in Research**

We/I would like to invite you to participate in a web-based online survey. The survey is part of a research study whose purpose is \_\_\_\_\_. This survey should take about \_\_\_\_\_ *[minutes/hours/sessions/etc.]* to complete.

We/I are asking you to participate in this study because you are \_\_\_\_\_. **You must be at least 18 years old to take this survey.**

**The decision to participate in this research project is voluntary.** You do not have to participate and you can refuse to answer any question. Even if you begin the web-based online survey, you can stop at any time.

**There are no foreseeable risks or discomforts to you for taking part in this study.**

**OR**

**The possible risks or discomforts of the study are minimal.** You may feel a little *[uncomfortable/embarrassed/sad/tired/etc.]* answering *[personal/sensitive/many/etc.]* survey questions.

**There are no direct benefits to you from participating in this study.** However, your responses may help us learn more about \_\_\_\_\_.

**You will not be paid for your participation in this study.**

**OR**

*[If participants will be paid or receive a gift, please state what the payment is and how it will be given. For example: As a token of our appreciation for completing the survey, you will be able to download a gift certificate for a free movie pass.]*

Your part in this study is anonymous to the researcher(s). However, because of the nature of web based surveys, it is possible that respondents could be identified by the IP address or other electronic record associated with the response. Neither the researcher nor anyone involved with this survey will be capturing those data. Any reports or publications based on this research will use only group data and will not identify you or any individual as being affiliated with this project.

**If you have any questions regarding electronic privacy,** please feel free to contact Glenn C. Hill, Director of Information Security and Identity Services, via phone at 617-373-7718, or via email at [privacy@neu.edu](mailto:privacy@neu.edu).

**If you have any questions about this study,** please feel free to contact \_\_\_\_\_ *[name and contact information]*, the person mainly responsible for the research. You can also contact *[name and contact information]*, the Principal Investigator.

**If you have any questions regarding your rights as a research participant,** please contact Nan C. Regina, Director, Human Subject Research Protection, 960 Renaissance Park, Northeastern University, Boston, MA 02115. Tel: 617.373.7570, Email: [irb@neu.edu](mailto:irb@neu.edu). You may call anonymously if you wish.

**By clicking on the survey link below you are indicating that you consent to participate in this study. Please print out a copy of this consent form for your records.**

http://\_\_\_\_\_

Thank you for your time.



[Name of Investigator]

## APPENDIX E

### CATEGORIES OF REVIEW

#### I. Exempt

**Note:** *All research activities must be reviewed by [Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#) even when categorized as "exempt" status.*

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, qualifies as exempt *unless*: (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects identified (must be anonymous); and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2, i, ii, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.



6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## **II. Expedited Review**

### **Applicability**

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

According to [45 CFR 46 102\(i\)](#), 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.”

- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) IRB's are reminded that the standard requirements for informed consents (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

### **Research Categories**



- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - (b) from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and



effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:
  - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - (b) where no subjects have been enrolled and no additional risks have been identified; or
  - (c) where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

- 
1. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson



from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2. Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998

### **III. FULL COMMITTEE REVIEW**

Research that requires review by the full committee includes studies that are more than [minimal risk](#) [45 CFR 46.102 (i)] for the participant, include vulnerable populations, cannot be classified in the expedited or exempt categories, or otherwise determined by HSRP.



**APPENDIX F**  
**PROTECTION OF PARTICIPANTS IN BEHAVIORAL AND**  
**SOCIAL SCIENCES RESEARCH**

See

[http://obssr.od.nih.gov/about\\_obssr/BSSR\\_CC/BSSR\\_definition/definition.aspx](http://obssr.od.nih.gov/about_obssr/BSSR_CC/BSSR_definition/definition.aspx)



## **APPENDIX G APPLICATION ASSISTANCE FOR USE OF HUMAN SPECIMENS\* IN RESEARCH**

[Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#) review is necessary whether you collected these samples or you received the samples from another source. Upon review, HSRP will determine whether the research qualifies for exemption or needs approval. Please use the standard [Application for Approval form](#) for HSRP review.

The National Institutes of Health website includes "[FAQs about Research Using Human Specimens, Cell Lines or Data Information](#)" and is very helpful in presenting issues involved in using human specimens. It may assist you in preparing your submission. The URL can be accessed at: [http://grants.nih.gov/grants/policy/hs/faqs\\_specimens.htm](http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm).

**If you are collecting the samples yourself**, all the questions on the standard form need to be answered.

Below is a partial list of issues that may need additional consideration in your submission. The nature of your research will determine the level of protection and information that are necessary. For example, genetic information that can be linked to a particular individual requires judicious management. Further information may be requested.

### **Qualifications of personnel conducting sampling procedure**

### **Infection control in obtaining and managing samples**

### **Identification of samples**

Anonymous if possible

Use coding if anonymity not feasible. Describe coding and linkage procedures.

Documentation that links codes to names should be maintained separately.

Destroy links to identifiers as soon as possible.

Describe confidentiality in entering and maintaining data

### **Use of samples**

Identify what the samples will be used for

State the limits of their use

*For example, The blood will be tested for the presence of.... No other testing will be done. All unused blood will be destroyed within two weeks of testing.*

Who will have access to this information?

Who will be informed about the results of testing? Other researchers? Physician?

Subject? Subject's family?



### **Disposition of samples**

Will the samples be destroyed? When? If not, why not?

**If you will obtain human specimens from another source**, you will use the standard application form but some of the questions will not apply. Include:

**Source of the samples.** For example, Brigham and Womens Hospital, or a tissue bank  
Provide a document from the site about the source of the samples. If specimens are collected prospectively, a copy of the Informed Consent and Health Information Use and Disclosure Authorization to be used must be included. For example, if specimens are discarded tissues following surgery for lung cancer, you will need to provide a copy of the IRB approval from the hospital and a copy of the Informed Consent and Health Information Use and Disclosure Authorization used (not each signed consent). If tissues are from a tissue bank, provide documentation from the bank about the samples.

### **Are the samples identifiable?**

Are the samples from deceased persons?

Are the samples identified by name? Are they identified with a code that links to an individual?

Is there any way that the sample can be linked to an individual by you *or anyone else*?

### **If these specimens had**

- a) **already been collected at the time you wrote your protocol, and**
- b) **there is no way that the specimen can be linked to any individual by you or anyone else, and**
- c) **you provide documentation of the source of the samples; the study will qualify as Exempt. See *Policies\*\**, Appendix E, Exempt #4, Categories of Review**

For samples that are identifiable, provide information from Identification, Use, and Disposition of Samples from above.

**If the study does not qualify for exemption as identified above, it may qualify for expedited review by the Chair of the Northeastern University Institutional review Board if it is determined by HSRP to be minimal risk. See *Policies\*\** Appendix E Expedited Status #5. If it cannot be expedited, it will be reviewed by the full committee.**

\*Examples of human specimens are: blood, cells, saliva, tissue samples, hair or nail clippings, DNA

\*\* *Policies and Procedures Concerning the Protection of Human Subjects*  
[http://www.research.neu.edu/facts\\_rates\\_forms\\_policies/policies/documents/humansubjectspolicymanual.pdf](http://www.research.neu.edu/facts_rates_forms_policies/policies/documents/humansubjectspolicymanual.pdf).



## APPENDIX H SECONDARY ANALYSIS OF DATA

Secondary analysis of data is using data that has already been collected to answer a research question.

If your research involves only the use of records or other data on living individuals, and no interaction, survey or observation of individuals, some of the questions on the Application for Approval will not apply.

In any case, your study still requires review by [Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#). However, it may qualify for an exemption (determined only by HSRP) if the following conditions are met:

1. the data is existing, i.e., the data has already been collected and is “on the shelf” at the time you write your protocol,

AND

2. Either
  - a. the data, documents, records are publicly available (e.g., city records),OR
  - b. the data is recorded by the investigator in such a way that **the subjects cannot be identified** either directly or indirectly through identifiers linked to the subject

If you think your study may qualify for this exemption, complete the [Request for Approval](#) sections A – G and N. Then provide information about the source of your data to document how the above criteria have been met. If the source is not public, you will need written documentation from the site in most cases. HSRP will make the final determination if the study is exempt. Exemptions are not determined by the investigator.

If your study does not qualify for an exemption, complete the [Request for Approval](#). Write n/a for sections that do not apply; K – N require response. Provide information about the source of the data, the purposes and means by which it was originally collected, identifying information that is used, and the means by which confidentiality is maintained by the current source and the means by which you will maintain confidentiality. You will need to provide written approval/permission from the site.

*For example, if you want to use student records or medical records, you need written permission/ IRB approval from the school or hospital. State exactly which records/information you want. Describe the identifiers currently on the records and the procedures you will be using to identify or de-identify the records.*



## APPENDIX I INSTRUCTIONS FOR NU ADMINISTRATIVE SURVEYS

Administrators at Northeastern frequently conduct survey research to evaluate and improve university programs and services. Most of these surveys are anonymous and do not request sensitive information and therefore do not require review by [Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#). Occasionally, administrators need to include confidential, sensitive information and/or require the identity of the respondent in order to evaluate a program. In this situation, the survey must be reviewed and approved by the NU IRB before administration.

To assist in determining which surveys require HSRP review, the following criteria have been developed.

If you hold an administrative position at Northeastern University and your survey meets *all three* of the following criteria, you do *not* need to submit your survey to the Office of Human Subject Research Protection for review:

1. The purpose of the administrative survey is to develop or evaluate services or programs provided by Northeastern University for Northeastern students, staff, faculty, or alumni, and the results are for internal purposes only (not for publication),

*and*

2. The surveys are anonymous, that is, the survey responses cannot be connected in any way with the person who provided them. No names, social security numbers, codes, or other identifiable information, including demographics, can identify the individual,

*and*

3. The surveys do not collect sensitive or personal information on the individual or his/her family, such as health issues, financial information, illegal behavior, substance abuse, emotional problems, immigration status, or opinions that may potentially cause embarrassment or other negative consequences etc. \*

If your survey meets all three of the criteria, you may conduct your survey without review by HSRP.

**However, if your survey does not meet all three criteria, you will need to submit it for HSRP review and approval before administration.** Send a copy of the survey to [Northeastern University's Office of Human Subject Research Protection](#). Attach an explanation of the purpose of the survey and who will be asked to complete it. Include your name, department and contact information. We will review it and let you know if you can proceed with the survey or if we need further information. Please provide sufficient time for DRI review before your intended administration date.

If you have any questions, please contact Nan C. Regina, Director, Human Subject Research Protection at [n.regina@neu.edu](mailto:n.regina@neu.edu) or 617-373-4588.

\*These criteria apply to survey research only. They do not apply to personal information that Northeastern University must collect in order to provide student or employee services, such as medical history at Lane Health Center, intake data at the Center for Counseling and Student Development, financial information for Financial Aid office, HRM, etc.



**APPENDIX J**  
**DE-IDENTIFICATION OF HEALTH INFORMATION**  
**CERTIFICATION**

***DO NOT COMPLETE IF AUTHORIZATION WILL BE OBTAINED OR WAIVER OF AUTHORIZATION IS REQUESTED***

IRB Code #	Study	
PI Name		
Title of Study		

Research which involves the use of “de-identified” Protected Health Information (PHI)\* is exempt from HIPAA requirements. Identifiers include:

- Name
- All geographic subdivisions smaller than a state (street address, city, county, precinct)  
Note: zip code or equivalents must be removed, but can retain first 3 digits if the geographic unit to which the zip code applies if the zip code area contains more than 20,000 people
- For dates directly related to the individual, all elements of dates, except year. (date of birth, admission date, discharge date, date of death)
- All ages over 89 or dates indicating such an age
- Telephone number
- Fax number
- Email address
- Social Security Number
- Medical Record Number
- Health Plan Number
- Account Numbers
- Certificate or license numbers
- Vehicle identification/serial numbers including license plate numbers
- Device identification/serial numbers
- Universal Resource Locators (URL’s)
- Internet Protocol addresses (IP’s)
- Biometric Identifiers
- Full face photographs and comparable images
- Any other unique identifying number, characteristic or code

I certify the protected health information (\*PHI) received or reviewed by research personnel for the research project referenced above does not include any of the 19 identifiers listed above.

Principal Investigator Signature	Date

\* PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual



## **APPENDIX K DATA USE AGREEMENT**

*This Data Use Agreement (“Agreement”) is made and entered into as of this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_ by and between Northeastern University (“Covered Entity”), and \_\_\_\_\_ (“Data Recipient”).*

### **WITNESSETH:**

*WHEREAS, Covered Entity may Disclose or make available to Data Recipient, and Data Recipient may use, disclose, receive, transmit, maintain or create from, certain information in conjunction with research; and*

WHEREAS, Covered Entity and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and regulations promulgated thereunder; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information disclosed or made available to Data Recipient and certain information that Data Recipient Uses, Discloses, receives, transmits, maintains or creates, from Covered Entity.

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

### **A. DEFINITIONS**

*Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.*

1. Individual shall have the same meaning as the term “individual” in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.

2. Limited Data Set shall have the same meaning as the term “limited data set” in 45 CFR 164.514(e) of the Privacy Rule.

3. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

4. Protected Health Information or PHI shall have the same meaning as the term “protected health information” in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by Data Recipient from Covered Entity.



5. Required by Law shall have the same meaning as the term “required by law” in 45 CFR Sect. 164.501 of the Privacy Rule.

**B. SCOPE AND PURPOSE**

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose certain PHI to the Data Recipient.

2. Except as otherwise specified herein, Data Recipient may make all Uses and Disclosures of the Limited Data Set necessary to conduct the research described herein: \_\_\_\_\_ (include a brief description of the research) \_\_\_\_\_ (“Research Project”).

3. In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, \_\_\_\_\_ include: \_\_\_\_\_.

**C. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT**

1. Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.

2. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.

3. Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery.

4. Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.

5. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual.

6. Data Recipient will indemnify, defend and hold harmless Covered Entity and any of Covered Entity’s affiliates, and their respective trustees, officers, directors, employees and agents (“Indemnitees”) from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney’s fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient’s control.



## **D. TERM AND TERMINATION**

The provisions of this Agreement shall be effective as of the earlier of Effective Date or April 14, 2003 and shall terminate when all of the Limited Data Set provided by Covered Entity to Data Recipient is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy the Limited Data Set, protections are extended to such information, in accordance with the termination provisions in this Section.

## **E. MISCELLANEOUS**

1. A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.

2. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and HIPAA.

3. The respective rights and obligations of Data Recipient under Section C of this Agreement shall survive termination of this Agreement.

4. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

5. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the parties' specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is Used or Disclosed pursuant to this Agreement.

6. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

7. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.

8. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of Data Recipient to Covered Entity shall apply to the breach of any covenant in this Agreement by Data Recipient.

9. This Agreement shall be construed in accordance with and governed by the laws of the Commonwealth of Massachusetts.



IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above.

NORTHEASTERN UNIVERSITY

[DATA RECIPIENT]

\_\_\_\_\_

\_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_



**APPENDIX L**  
**CONTINUING REVIEW/STUDY COMPLETION FORM**

**Institutional Review Board (IRB)**  
Continuing Review/Study Completion Form (CRF)

NU IRB No. \_\_\_\_\_ Date \_\_\_\_\_ Dept. \_\_\_\_\_

Project Title: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_ Tel. \_\_\_\_\_

Mailing Address: \_\_\_\_\_ Email: \_\_\_\_\_

Circle whether Principal Investigator is: Faculty Staff Other

If student research, name of student \_\_\_\_\_ Tel. \_\_\_\_\_

Mailing Address: \_\_\_\_\_ Email: \_\_\_\_\_

Original IRB Approval Date: \_\_\_\_\_ Most Recent IRB Approval Date: \_\_\_\_\_

Project Begin Date: \_\_\_\_\_ (MM/DD/YYYY) Project End Date: \_\_\_\_\_  
(MM/DD/YYYY)

Source of funding for project: \_\_\_\_\_ Is project funded through RAF? \_\_YES \_\_ NO

**Project Status (check one)**

\_\_\_\_\_ The project did not start and is not in operation.

**Do you plan to start this project?** \_\_\_\_ YES \_\_\_\_ NO

**IF YES, YOU MUST INCLUDE NEW, UNSTAMPED CONSENT FORMS, DEBRIEFING STATEMENTS (if applicable), AND RECRUITMENT MATERIALS WITH THIS CRF. YOUR CRF WILL BE RETURNED TO YOU AND PROCESSING WILL BE DELAYED WITHOUT THESE FORMS.**

**(Skip all questions. Sign, date & return form.)**

\_\_\_\_\_ The project is ongoing and open to enrollment. **IF YES, YOU MUST INCLUDE NEW, UNSTAMPED CONSENT FORMS, DEBRIEFING STATEMENTS (if applicable), AND RECRUITMENT MATERIALS WITH THIS CRF. YOUR CRF WILL BE RETURNED TO YOU AND PROCESSING WILL BE DELAYED WITHOUT THESE FORMS.**

**(Answer all questions. Sign, date & return form.)**

\_\_\_\_\_ The project is ongoing but is closed to enrollment. **(Answer all questions. Sign, date & return form.)**

**If yes, choose one:**

\_\_\_\_\_ Active follow-up continues

\_\_\_\_\_ Long term follow up continues

\_\_\_\_\_ Ongoing analysis only

\_\_\_\_\_ The project concluded during the last year. Date of completion \_\_\_\_\_ (MM/DD/YYYY)  
**(Attach a summary of the results. Answer all questions. Sign, date & return form.)**

1. Identify other participants (individuals, institutions, agencies) involved in the project. **Renewed approvals from involved sites are required for NU renewal of approval.**
2. How many human subjects do you plan to use in your project? \_\_\_\_\_ How many human subjects have participated to date? \_\_\_\_\_ How many subjects have withdrawn from the project to date? \_\_\_\_\_ **Explain reasons for withdrawal:**



3. Is the original study protocol being followed as approved?    Yes        No        **If no, explain:**
  
4. Have any subjects expressed any complaints about the project? Have any subjects claimed to have suffered harm or injury?    YES        NO        **If yes, explain:**
  
5. Have there been any significant new findings (favorable or unfavorable) that might influence subjects' willingness to continue as subjects:        YES        NO        **If yes, explain:**
  
6. Progress Report: Summarize the essential aspects of progress or results to date. **You may enclose an abstract or other report.**
  
7. Is there a record of the names of all subjects who participated in this study?        Yes        No
  - a. If yes, where is the record kept and is it secure?
  
  - b. If no, why not?
  
8. Does the PI have signed copies of the Informed Consent statement on file:        Yes        No
  - a. If yes, where are they kept?
  
  - b. If no, why not?
  
9. If you receive federal funding for this research, please record, **on a separate sheet**, the names of all current research staff working on this project at each site. Indicate beside each name whether this person has completed the required National Institutes of Health (NIH) training.  
  
 Documentation of NIH training (<http://phrp.nihtraining.com>) must be on file at HSRP. For sites with their own IRB approval, you may provide a letter from the IRB office that the research staff at that site have completed the training.

***Please sign:***

Principal Investigator \_\_\_\_\_ Date \_\_\_\_\_

Student (if applicable) \_\_\_\_\_ Date \_\_\_\_\_

**Please return completed form to:**    Office Human Subject Research Protection  
 960 Renaissance Park, Northeastern University  
 Boston, MA 02115  
 Tel: 617.373.7570; Fax: 617.373.4595

**Note: On site monitoring procedures may also be conducted by NU IRB.**



**APPENDIX M**

**N O R T H E A S T E R N U N I V E R S I T Y**

**Institutional Review Board (IRB)**

Continuing Review/Study Completion Form (CRF) - **Category of Review: Expedited #5**

NU IRB No. \_\_\_\_\_ Date \_\_\_\_\_ Dept. \_\_\_\_\_

Project Title: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_ Tel. \_\_\_\_\_

Mailing Address: \_\_\_\_\_ Email: \_\_\_\_\_

Circle whether Principal Investigator is: Faculty Staff Other

If student research, name of student \_\_\_\_\_ Tel. \_\_\_\_\_

Mailing Address: \_\_\_\_\_ Email: \_\_\_\_\_

Original IRB Approval Date: \_\_\_\_\_ Most Recent IRB Approval Date: \_\_\_\_\_

Project Begin Date: \_\_\_\_\_ (MM/DD/YYYY) Project End Date: \_\_\_\_\_  
 (MM/DD/YYYY)

Source of funding for project: \_\_\_\_\_ Is project funded through RAF?  YES  NO

**Project Status (check one)**

The project did not start and is not in operation. **Do you plan to start this project? YES NO**

The project is active with ongoing analysis of data, documents, records, or specimens that were originally collected or will be collected solely for non-research purposes.

The project concluded during the last year. Date of completion \_\_\_\_\_ (MM/DD/YYYY)

10. Identify other participants (individuals, institutions, agencies) involved in the project. **Renewed approvals from involved sites are required for NU renewal of approval.**

11. Is the original study protocol being followed as approved? Yes No **If no, explain:**

12. Progress Report: Please summarize the essential aspects of progress or results to date. **You may enclose an abstract or other report.**

13. If you receive federal funding for this research, please record, **on a separate sheet**, the names of all current research staff working on this project at each site. Indicate beside each name whether this person has completed the required National Institutes of Health (NIH) training.

Documentation of NIH training (<http://phrp.nihtraining.com>) must be on file at HSRP. For sites with their own IRB approval, you may provide a letter from the IRB office that the research staff at that site have completed the training.

**Please sign:**

Principal Investigator \_\_\_\_\_ Date \_\_\_\_\_

Student (if applicable) \_\_\_\_\_ Date \_\_\_\_\_

Please return completed form to: Office of Human Subject Research Protection  
 960 Renaissance Park, Northeastern Univ.  
 Boston, MA 02115  
 Tel: 617.373.7570; Fax: 617.373.4595

Note: On site monitoring procedures may also be conducted by NU IRB.



## Memorandum

**To:** NU Personnel Involved in Human Subject Research  
**From:** Stephen W. McKnight, Acting Vice Provost for Research  
**Subject:** Required Training for Research Involving Human Subjects  
**Date:** October 16, 2008

Northeastern University is committed to conducting research that follows the highest ethical standards. When research is conducted with human subjects, it is imperative that the Institution provide full protection and respect for each participant in *every* project. Northeastern University has signed an Assurance with the Office of Human Research Protections (OHRP), Department of Health and Human Services, in which the university states that it will fully comply with all federal guidelines regarding the protection of human subjects. *Compliance with these standards is mandatory for all faculty, staff, and students during the conduct of research, whether funded or unfunded, involving human subjects.*

Training in ethical standards for human subject research has long been required for NIH-funded studies. **Northeastern University is now requiring completion of this training for all human subject research, regardless of whether or not investigators have received funding to support their project. This requirement will be effective as of November 15, 2008 for all new protocols.**

The web site address for this training may be found at the following address: <http://phrp.nihtraining.com/users/login.php>. Once the training has been successfully completed, researchers will receive a certificate which should be printed out. A copy of this certificate should be included with protocol materials that are submitted to the Division of Research Integrity.

Human subject research includes:

- i) Data through intervention or interaction with an individual (i.e. interviews, surveys, clinical testing, or any other physical intervention or personal interaction). Anonymous classroom surveys for pedagogical or instructional purposes are generally not included if they don't inquire about sensitive or illegal activities.
- ii) Identifiable private information (i.e. medical or school records, legal or insurance information, private government records).
- iii) Human tissue, fluids, or DNA *even if you received them from another source.*

Faculty, staff, and students are reminded that all research and instruction projects involving human subjects or data collected from human subjects must be reviewed and approved by the NU IRB prior to the start of any project. This includes research conducted by faculty or by students (including theses, dissertations, etc.) whether on campus or off-campus, whether funded or unfunded. Investigators participating in collaborative research approved at another site must also receive Northeastern University approval. Any deviation or omission on the part of an investigator places the University at risk of losing its status as a site for federally-funded research.

**All protocol requests for research concerning human subjects should be addressed to:  
Nan Clark Regina, Director, HSRP, (x 4588, 960 Renaissance Park).**

Further information is available at [http://www.research.neu.edu/research\\_integrity/](http://www.research.neu.edu/research_integrity/)

Thank you in advance for your commitment to this effort.



## POLICY FOR CLASSROOM RESEARCH INVOLVING FACULTY AND STUDENTS

### A. Introduction

This guideline addresses students conducting research. The Northeastern University IRB (NU-IRB) is guided by [45 CFR 46](#) (Common Rule) in its definition of research as being a “systematic investigation designed to develop or contribute to generalizable knowledge.” The IRB distinguishes between research conducted in a classroom as part of the learning experience (“Student Research”) from research conducted to add to generalizable knowledge or a professional body of knowledge (clinical research, thesis, or dissertation work). The purpose of this policy is to clarify when student research must be reviewed by the IRB, or if it is deemed as “Student Research,” who is responsible for reviewing that research.

### B. Definitions

1. **Dissemination** means the distribution of findings and includes, but is not limited to, masters and doctoral theses/dissertations, presentation at a scientific meeting or conference, submission to or publication (paper or electronic) in a scientific journal, and posting on the Internet.
2. **Human subject** 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.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3. **Institutional Review Board (IRB)** means the Northeastern University board which reviews and approves the initiation of, and conducts periodic reviews of, research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.
4. **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 of healthy individuals.



5. **Student Research** means any observation or intervention, including administration or survey or interview questions, by a student as part of a course which is designed to develop or contribute to student learning or class discussion, but which will not lead to generalizable knowledge or publication/dissemination of findings outside of the classroom.

6. **Student Researcher** means any student enrolled in a course at Northeastern University who conducts research on human subjects as an assignment or project within a course, excluding a master's or doctoral theses research which must be under NU-IRB procedures.

### **C. Policy**

1. Student research projects that meet ALL of the conditions stated below may be conducted under the supervision of the faculty member without submitting a protocol to the IRB.

2. Projects that do not meet all of these conditions must be submitted to the IRB for review. [http://www.northeastern.edu/research/research\\_integrity/human\\_subjects/](http://www.northeastern.edu/research/research_integrity/human_subjects/).

Research conducted by students, graduate or undergraduate, as a part of classroom assignments does not usually fall under the federal regulation 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 NU-IRB submission and approval.

a. The class project must meet the definition of classroom research/student research. This is defined as a project which:

- is a normal part of the student's coursework;
- is supervised by a faculty member;
- has as its primary purpose the development of the student's research skills;
- does not present more than minimal risk to participants or to the student investigator;
- does not include any persons as research subjects under the age of 18;
- does not include any persons as research subjects who are classified as part of a vulnerable populations according to Federal regulations (see below);
- is not "genuine research" that is expected to result in publication or some other form of public dissemination;



NOTE: This policy applies to student class assignments only. Those independent research projects conducted by students, such as theses, honors projects, and independent study projects, that collect data through interactions with living people or access to private information DO fall under the jurisdiction of the IRB. Application to the IRB for these student research projects must include overall responsibility by a faculty member who will be named as the Principal Investigator of the project.

b. Student research projects must meet all the criteria for an Expedited Review as defined in the Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>. If the faculty member has concerns or doubts, he/she should consult with the Office of Human Subjects Research.

c. Please note that *even if the intent is to not produce generalizable knowledge, if a special population or sensitive topic area is part of the project, the student's project cannot qualify for general approval and, therefore, DOES require NU-IRB approval.*

Categories of sensitive information include information:

- 1) Relating to sexual attitudes, preferences or practices;
- 2) Relating to use of alcohol, drugs or other addictive products;
- 3) Pertaining to illegal conduct;
- 4) That if released could reasonable damage an individual's financial standing, employability, or reputation within the community;
- 5) That would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- 6) Pertaining to an individual's psychological well-being or mental health;
- 7) Genetic Information.

Categories of special subject population:

- 1) Minors (under eighteen years of age).
- 2) Fetuses or products of labor and delivery;
- 3) Pregnant women (in studies that may influence maternal health);
- 4) Prisoners;
- e) Individuals with a diminished capacity to give informed consent.

d. Faculty teaching research methods and 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; and to teach these practices and principles to students. Faculty will be responsible for ensuring that all student research projects are conducted in accordance with federal regulations and principles regarding protection of human subjects in research.

e. Faculty who will be Principal Investigators on classroom research projects must complete the NIH Computer-Based Training module which may be found at the following address: <http://phrp.nihtraining.com/users/login.php>.



### 3. Thesis/Dissertation Research

Thesis and dissertation projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the NU-IRB.

#### D. Tips for Faculty

Please note that, consistent with University policy, all teaching assignments involving human subjects must respect the rights and welfare of all individuals involved. The following suggestions for the faculty members provide guidance concerning student classroom projects:

**1. Consider the nature and intent of the activity.** If the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge -- an indication of which is intent to publish the data -- then the student classroom project is probably research and needs to be individually reviewed and approved by the IRB.

**2. IRB approval cannot be made retroactive.** If there is any likelihood that the results of the project might later be used for research that does lend to generalizable knowledge (for example, a presentation to a group other than the class), IRB approval must be sought prior to conducting the research. IRB approval cannot be granted retroactively.

**3. Minimize risks whenever possible.** Faculty members should help students understand that they are obligated to minimize risks for human subjects with whom they interact during the completion of their assignments. Depending on the circumstances, faculty members may find some of the following suggestions for students helpful:

- Have students take the NIH on-line training on human subject protection before collecting information from others.
- Encourage the use of anonymous data collection so that data is not linked to specific individuals.
- Have information identifying individuals kept separately from the information collected from those individuals.
- Collect project data at the end of the course, or within a short time afterward, and request all copies in the student's possession be destroyed.
- Encourage the use of unsigned consent forms.

**Ask for help!** Ask the Office of Human Subject Research Protection for guidance when you are unsure of what review process is needed for a student classroom project. Their contact information may be found at [http://www.northeastern.edu/research/research\\_integrity/human\\_subjects/](http://www.northeastern.edu/research/research_integrity/human_subjects/). Or you can call Nan C. Regina, Director of the Office of Human Subject Research Protection at 617-373-4588.