



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:

- DSPA (Division of Sponsored Projects Administration)
- 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 and <http://ohsr.od.nih.gov/guidelines/45cfr46.html>, respectively.