Human Subject Q & A

Are you conducting research with human subjects, such as clinical testing, surveys, human tissue studies, etc.?

If you are, be aware that Title 45 Code of Federal Regulations Part 46.102(f) defines a "human subject" as a living individual about whom an investigator obtains:

1. data through intervention or interaction with the individual, (such as, interviews, surveys, clinical testing, or any other physical intervention or personal interaction), or,
2. 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 that 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.

What research requires review by the Northeastern University Institutional Review Board (NU IRB)?

All research involving human subjects, as described above, that is conducted by faculty, staff or students of Northeastern University, whether conducted on-campus or off-campus, requires review. 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.

My research is not federally funded. Do the federal regulations governing research still apply to it?

Yes. Northeastern University has elected to apply the protections of the federal regulations (45 CFR 46) to all of our human subject research regardless of its source of support, or lack thereof.

What are the training requirements for conducting human subject research with funding from the National Institutes of Health (NIH)?

All Northeastern University investigators seeking funding from NIH must satisfy the NIH training requirement before an approved study may be initiated. The NIH Office of Extramural Research web-based tutorial "Protecting Human Research Participants" <http://phrp.nihtraining.com> satisfies the human subjects training requirement for obtaining Federal Funds.

Investigators must include a copy of the certificate of completion for this web-based tutorial with their protocol submissions.

How do I get approval for my research?

Read the Policies and Procedures Concerning the Protection of Human Subjects and the application forms to understand your responsibilities as an investigator. These may be found on the web site: http://www.research.neu.edu/facts_rates_forms_polices/policies/documents/humansubjectspolicymanual.pdf. Once you have submitted your application, a review will be conducted to ensure that your study has documented procedures in place, in accordance with federal guidelines, that provide adequate protection for each study subject.

How long does it take to get approval?

Investigators are responsible for allowing a minimum of four weeks for the review process. (This means that you should apply **at least** one month before your anticipated start date.) The NU IRB meets monthly to review protocols. Depending upon the nature of the research, some studies may be reviewed and approved independently by the Chair of the NU IRB. Other studies may require review by the full committee.

May I make changes to the protocol after it has been approved?

Modifications to the approved protocol or informed consent may be submitted in writing to the NU IRB. **Written approval must be received prior to instituting any change(s).**

How long is the approval valid?

Federal regulations stipulate that approved research requires continuing NU IRB review at least once a year. It is the responsibility of the investigator to request renewed approval, allowing sufficient time for review. If the renewal process is not completed by the expiration date, the project loses approval and the study cannot continue.

For more information, please contact:

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Web Site References:

NU IRB information
http://www.research.neu.edu/research_integrity/human_subjects/review_board/

NIH human subject research training
http://phrp.nihtraining.com

Office for Human Research Protection
http://www.hhs.gov/ohrp/

Office of Research Integrity (Federal Government)
http://ori.dhhs.gov/