Human Subject Research Protection
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- Protect the rights of human subjects
- Assess the risks and benefits of proposed research
- Ensure confidentiality of information obtained from research subjects
“Research” means a systematic investigation designed to produce generalizable knowledge.
A “human subject” is a living individual about whom an investigator obtains either
(1) Data through intervention or interaction with the individual;
(2) Identifiable private information
In order to conduct your research in accordance with these regulations, you must evaluate whether you or any designee obtain:

- **Data** through intervention or interaction with an individual (i.e. interviews, surveys, clinical testing, or any other physical intervention or personal interaction);

- **Identifiable private information** (i.e. medical or school records, legal or insurance information, private government records);

- **Bodily materials** (i.e. cells, blood or urine, tissues, organs, hair or nail clippings, saliva, DNA) *even if you received them from another source.*
As part of the initial review, HSRP assigns protocols to Exempt, Expedited Review or Full Committee Review.

Research categorized as *Exempt* or *Expedited* involves less than minimal risk or minimal risk.

Studies involving greater than minimal risk require review by the full IRB.
“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)
Investigator Responsibilities

- Application
- Assurance of Principal Investigator
- Consent Form (signed/unsigned, etc.)
- Applicable appendices
  - Recruitment ads, posters, etc.
  - Letters from Participating Sites

As well as ongoing oversight of the protocol!!
Projects with Multiple Sites in Which Human Subjects are Involved

- Generally require IRB approval from that site
- When NU is the Prime, oversight important
- Possible to execute IRB Authorization Agreement which allows reliance upon another IRB
Once you have received IRB approval

1. Informed consent form bearing the IRB approval stamp must be used when recruiting participants into the study;

2. The investigator must notify IRB immediately of unexpected adverse reactions, or new information that may alter our perception of the benefit-risk ratio;

3. Study procedures and files are subject to audit any time;

4. Any modifications of the protocol or the informed consent as the study progresses must be reviewed and approved by this committee prior to being instituted;

5. Continuing Review Approval for the proposal should be requested at least one month prior to the expiration date above;

6. This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.
Contact Info

• Nan Clark Regina, Director, HSRP
  Tel. (617) 373-4588 | Fax (617) 373-4595 | Email: n.regina@neu.edu

• Andrea B. Goldstein, Coordinator, HSRP
  Tel. (617) 373-7570 | Fax (617) 373-4595 | Email: an.goldstein@neu.edu

• Kate Skophammer, IRB Coordinator, College of Professional Studies
  20 Belvidere, 360 Huntington Avenue, Boston, MA 02115
  Tel. (617) 373-6659 | Fax (617) 373-6600 | Email: k.skophammer@neu.edu

http://www.northeastern.edu/research/hsrp/