

## Protecting Human Research Subjects: A Guide for Students

The requirements to protect human subjects apply to a much broader range of research studies than many student investigators realize.

If you are conducting research using human subjects for a class project with the intent to publish your results, or for a Master's or honors thesis, you must seek IRB (Institutional Review Board) approval or exemption *prior to* data collection.

*IRB approval must precede initiation of any work involving human subjects. There is no retroactive approval for previously collected data. Failure to seek approval for your thesis or research may invalidate your study or result in your inability to graduate.*

### What Constitutes Human Subject Research?

- Studies that use people to test *devices, products, or materials* that have been developed through research; or to evaluate environmental alterations, for example, weatherization options or habitat modifications.
- Studies that collect data through *intervention or interaction* with individuals. Intervention includes not only physical procedures (e.g., drawing blood) but also manipulation of a subject's environment (e.g., surveys, questionnaires, interviews, and focus groups). Examples of this type of research include: the evaluation of teaching methods and programs; internet surveys about alcohol consumption; deception research; research involving risky behaviors or attitudes; and open-ended interviews with minors about family values in a foreign country. Data collection using non-individually identifiable information may be **exempt**.<sup>1</sup> (Only the IRB has the authority to determine exemptions).
- Studies using *private information* that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- Studies that use *bodily materials* such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if you did not collect these materials for the study. However, such research may be considered *exempt* if materials are not personally identifiable. Only the IRB has the authority to make the exempt determination.
- Studies that produce *generalizable knowledge* about categories or classes of subjects from individually identifiable information.

If your research belongs to any of the above categories, you must comply with the Federal Regulations and Northeastern Illinois University policies for the protection of human subjects.

These requirements apply if the research is conducted using NEIU facilities or property, supported with NEIU funds, or performed by NEIU faculty, staff, or students.

## Human Subjects Research

The NEIU Institutional Review Board is responsible for making final decisions as to what constitutes human subjects research and how human subjects research protections must be implemented.

NEIU adheres to the Federal Regulation 45 CFR 46 Protection of Human Subjects<sup>2</sup> which states:



**RESEARCH** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**HUMAN SUBJECT** is 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 (for example, venipuncture) 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 readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

## NEIU Institutional Review Board

An IRB is a committee of scientists and nonscientists who review projects submitted by researchers.

The IRB at Northeastern Illinois University must review and approve research if it involves human subjects.

This process is designed to ensure the protection of the rights and welfare of human subjects by minimizing risks, selecting subject equitably, obtaining informed consent, and ensuring privacy and confidentiality.

IRB approval is valid for one year. If the research continues, the IRB must review and approve the study at least once a year.

**The investigator is required to notify the IRB if subjects experience:** physical injury, unexpected or adverse events, improper disclosure of private information, economic loss, and other harmful or potentially harmful occurrences.

## Informed Consent

Informed consent is the process of informing potential volunteers about the key facts of a research study.

The human subjects in your study must participate willingly, after having been adequately informed about the research.

If the human subjects in your study are part of a vulnerable population, such as prisoners or children, special protections are required. For more information on vulnerable populations, please consult the NEIU Office of Sponsored Programs ([www.neiu.edu/~sprogram](http://www.neiu.edu/~sprogram)) website.

Voluntary participation means that subjects have enough information to give true informed consent. Such information includes:

- *Purpose* of the research.
- *Benefits* of the research to society and, possibly, to the individual human subject.
- *Procedures* involved in the research.
- *Alternatives* available should a subject decide not to participate in the research.
- *All foreseeable risks or discomforts* to the subject. Note that these include not only physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- *Length of time* the subject is expected to participate.
- *Person to contact* for answers to questions; or in the event of a research-related injury or emergency; or questions about their rights as human subjects.
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive.
- Subjects' *right to confidentiality and right to withdraw* from the study at any time without any consequences.



Consent documents must be clearly written and understandable to subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be plainly defined. It is often recommended that the informed consent be written at the eighth grade reading level. The same recommendation applies to the assent forms for minors and study recruitment materials.

Informed consent may not include language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability or negligence. Templates for consent forms are available from the Office of Sponsored Programs website.

## Types of IRB Review

**Full Board (Convended) Review** – Some studies involve more than minimal risk<sup>3</sup> and merit Full Board Review. Minimal risk is defined as 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.

These studies require a review of the proposed research at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present.

**Expedited Review** – Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Expedited review is performed by the IRB chair, a designated voting member, or group of voting members rather than by the entire convened IRB.

**Exemption** – When it is determined that the study does not involve human subjects (as defined in 45 CFR 46) or the involvement of human subjects is in one of the six exempt categories listed in the Regulation (45 CFR 46.101(b))<sup>1</sup>, it is exempt. The exempt categories include certain educational practices and tests, study of existing data, public service programs and food evaluations. For more information about exempt categories, see the OSP website.

*Any research study involving human subjects thought to be exempt must be submitted to the IRB for a determination.*

## **Recommendation**

To avoid possible delays in approving your project and large amounts of paperwork, it is recommended that you design your project so that it will fall in the “exempt” category. To help ensure that projects can satisfy the requirements for exemption **AVOID** the following:

- Audio-taping of interviews;
- Collection of identifiers in recording data; quotation by name in reports.
- Interviews or interventions with vulnerable populations;
- Video-taping or photography of human subjects in field observations;
- Use of experimental techniques or deception.

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