Northwestern Health Sciences University

Institutional Data Collection Involving Human Subjects

A. Purpose

This policy establishes the basic principles for all data collection activities involving human subjects that are conducted at Northwestern Health Sciences University.

B. Revision History

Originally issued: January 2006

C. Persons Affected

All Northwestern Health Sciences University faculty, staff, and students involved in institutional data collection activities involving human subjects.

D. Related Documents

Institutional Data Collection Form

IRB application forms http://www.nwhealth.edu/institutional-review-board/application-forms/

E. Definitions

Data collection

A systematic gathering of information. May or may not meet the definition of "research."

Human subject

A living individual about whom a person obtains either

a) data through investigation or interaction with the individual or
b) identifiable private information

Research

A systematic gathering of information designed to develop or contribute to generalizable knowledge (i.e., will be accessible or presented outside the University or will be published).

F. Jurisdiction

Northwestern Health Sciences University has a Federalwide Assurance of Protection for Human Subjects file with the US Department of Health and Human Services, Office for Human Research Protections. Northwestern is responsible for maintaining a unified system of protections applicable to all human subjects research covered under the Assurance and implementing appropriate oversight mechanisms to ensure compliance with the policies of the IRB.

G. Policy

To fulfill its mission, NWHSU relies on data collection at several levels, including data collection activities that involve gathering information from human subjects. Recognizing this, and consistent with its commitment to valuing and protecting its human resources, NWHSU recognizes the need to ensure that **participants involved in any type of data collection activity are treated with respect**.

This policy identifies three types of institutional data collection involving human subjects:

1. Institutional data collection for non-research purposes
2. Institutional data collection for research purposes
3. Student data collection

1. Institutional data collection for non-research purposes

Institutional data collection for non-research purposes is the gathering of data from or about university students, faculty, staff, or alumni members by university departments or organizations, with the intent of

using the data solely for internal informational or quality assurance purposes or for required data collection purposes. That is, data collected will NOT be accessible (e.g., the Internet) or presented outside the University (e.g., professional meeting) or published (e.g., professional journal).

Examples

- Data collection to improve educational or other services or procedures at the university
- Data collection to ascertain the opinions, experiences, or preferences of the university community
- Data collection to characterize the university community

Often, such data is collected via:

- Student evaluations/surveys
- Alumni surveys
- Curriculum focus groups
- Employee satisfaction surveys/focus groups

Requirements

Unless potentially sensitive information is collected, Institutional data collection for non-research purposes does NOT require IRB approval. However, an Institutional Data Collection Form must be submitted to the IRB to be kept for their records.

If information on sensitive topics is being elicited, or if any unanticipated disclosure of responses outside the context of the data collection activity could place the subject at risk of criminal or civil liability or be damaging to the subject's reputation, employability, or financial standing, prior IRB approval is required. Examples would include collecting information on subjects' drug use, alcohol use, sexual behavior, health status, or illegal conduct.

NOTE: If it is uncertain whether or not information gathered for non-research purposes may at a future point contribute to generalizable knowledge, such as through a presentation, publication, or Internet access, IRB approval should be obtained prior to initiating the data collection activity. **Under federal policy, the IRB cannot grant retroactive IRB approval**.

2. Institutional data collection for research purposes

Institutional data collection for research purposes is the gathering of data from or about university students, faculty, or staff members by university departments or organizations, with the intention of contributing to generalizable knowledge. That is, data collected will be accessible or presented outside the University.

Examples

- Data collection through questionnaires, interviews, or focus groups with an intention to present the findings (e.g., professional meetings) or to publish the findings (e.g., professional journals/publications)
- Collaborative (multi-site) data collection activities planned and carried out on-campus with the intention of contributing to generalizable knowledge
- Research projects initiated elsewhere but involving Northwestern employees or students

Requirements

Institutional data collection for research purposes DOES require prior approval by the IRB. An IRB application must be submitted to the IRB. No part of the research involving human subjects (including recruitment efforts) may begin before IRB approval has been granted.

3. Student data collection

Student data collection activities involving human subjects may range from activities taking place entirely within the classroom or clinical setting to independent research and honors projects. Faculty members who assign or supervise data collection activities by students are responsible for ensuring that such activities are conducted in accordance with University policies and that students are qualified to safeguard the well-being of the subjects.

Requirements

The informal collection of information by students from respondents—for example, interviewing friends or relatives for purposes of class discussion or assignments—has no IRB requirement.

Student projects designed to provide hands-on experience or research training to students have no IRB requirement. Projects in this category are expected to be confined to the specific class and end at the termination of that class.

Student projects designed to add to generalizable knowledge through dissemination of results in publications or presentations beyond the classroom/clinical setting DOES require prior approval by the IRB. An IRB application must be submitted to the IRB.

NOTE: If it is anticipated that the class project will be used in other classes or published or presented beyond the classroom, IRB approval should be obtained prior to initiating the data collection activity.