



IRB Standard Operating Procedures		
SOP#: 11 Revision#:	Title: Data Collected Without Institutional Review Board Approval	Effective Date: January 26, 2021
Approved by:	Institutional Review Board	Approval Date: January 26, 2021

PURPOSE

All research involving human subjects reviewed by the Institutional Review Board (IRB) must be evaluated for issues in proposed study design and conduct that may affect the rights and welfare of human subjects, consistent with Federal Regulations, state and local laws, professional standards, and Northeastern Illinois University (University) rules and policy. The purpose of this Standard Operating Procedures (SOP) is to define the circumstances in which data are considered to have been obtained by researchers without IRB approval and to establish the consequences of obtaining data without IRB approval.

DEFINITIONS

Continuing noncompliance – instances in which an investigator engages in multiple occurrences of any level of noncompliance (serious or otherwise) and the IRB determines that the noncompliance involves deliberate disregard for IRB regulations.

Data - individually identifiable private data, specimens, or information in any format.

Generalizable knowledge - information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information.

Identifiable private information - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Minimal risk - 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.

Research - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Serious noncompliance - an action that potentially places participants at more than minimal risk and involves deliberate disregard for the regulations or the determinations of the IRB. Examples: beginning or continuing more than minimal risk research without IRB approval; serious misuse or non-use of approved consent forms; failure to secure IRB approval before introducing changes in an on-going protocol, when those changes potentially constitute more than minimal risk to the participants; or not reporting adverse events or unanticipated problems per University rules.

POLICY

Data obtained for human research activities in which the University is engaged are considered to have been collected without IRB approval when obtained under any of the following circumstances:

1. With no prior review or approval by the IRB;
2. With no informed consent from the subjects or their legally authorized representatives (and when the IRB had not approved a waiver of consent);
3. Using procedures that were not described in the IRB-approved consent document (and when the IRB had not approved a waiver for excluding the procedure from the consent document);
4. Over-enrollment of subjects (when the number of participating subjects exceeds the number approved for enrollment by the IRB);
5. After the expiration of IRB approval; or
6. After suspension or termination of IRB approval.

The IRB does not, and cannot, grant retroactive approval for use of data that was collected without IRB approval. Federal regulations allow IRB approval to be granted only when it is prior to the initiation of the research activities.

RESPONSIBILITIES

Procedures for Monitoring and Addressing Noncompliance

All faculty, staff, students, and administrators are responsible for supporting the ethical conduct of research involving human participants at the University. This includes reporting possible noncompliance promptly to the IRB Chair or Office of Research and Sponsored Projects (ORSP) so that it can be addressed, and educational and other corrective actions taken, if needed.

If a question arises as to whether a particular project was reviewed by the IRB or whether particular procedures were approved, questions should be posed to the IRB Chair or ORSP. A letter or email describing the IRB's concern is then prepared by the IRB Chair or ORSP offering the researcher who is noncompliant an opportunity to respond via email, in writing, at an informal conference, or at an IRB meeting, and specifying a time period within which the response must be provided.

If the researcher offers a timely and satisfactory explanation for the concern, the noncompliance process will be terminated and the researcher will be notified in writing. If the researcher offers an explanation that fails to satisfy the complaint, or if the investigator fails to respond within the specified time period, the IRB Chair, in consultation with the ORSP, will make a determination of whether the action appears to have involved deliberate disregard or lack of knowledge/awareness and whether the noncompliance is serious and/or continuing.

Consideration will be given to the length of time the researcher has been engaged in research, the extent and nature of previous involvement with the IRB, and any previous communications with the

IRB. All instances of noncompliance will be kept confidential, except when reporting within the University, ORSP, and/or sponsors is necessary.

Consequences of Noncompliance

Federal regulations ([45 CFR 46.113](#)) provide the IRB with the authority to suspend or terminate research that violates IRB requirements. Depending upon the nature and seriousness of the noncompliance activity, the IRB and the ORSP may take the following actions:

1. Require a response from the researcher with a plan for corrective actions;
2. Require the researcher to complete additional human participants protection training;
3. Initiate audits of the active protocols;
4. Require that research participants previously enrolled in the study be contacted and provided with additional information and/or re-consented;
5. Suspend or terminate the study;
6. Freeze sponsored research grant account;
7. Determine that data collected during noncompliance cannot be used for publication;
8. Require that a statement be included with all publications or research reports indicating that the research was not approved by the IRB;
9. Report the violation to the sponsor, university officials, and governmental agencies, (e.g., NIH);
or
10. Disqualify the researcher from conducting research involving human participants at the University.

In the case of serious or continuing noncompliance, the IRB and the ORSP will evaluate the researcher's qualifications to conduct human participant research. The IRB will also take remedial action, as necessary, regarding the welfare of the participants and the research data gathered in noncompliance. Further, the IRB may refer instances of serious or continuing noncompliance to the Provost, who may decide whether to impose disciplinary sanctions.

Regulations

[45 CFR 46.102](#)

Author Reference

NEIU IRB

[University of Washington, Data Collected Without IRB Approval](#)

[University of Northern Iowa, IRB Manual Noncompliance](#)

Contact Information

Please direct questions or concerns about this policy to:

Contact	Phone	E-Mail
IRB Office	773-442-4675	irb@neiu.edu
Dean of the College of Graduate Studies and Research	773-442-6012	gradstudies@neiu.edu

Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review.

Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.