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

Requests for exception to any portion of this poli