IRB Standard Operating Procedures		
SOP#: 16 **Revision#:**	**Title: Obtaining Informed Consent**	**Effective Date:** **October 13, 2020**
Approved By:	**Institutional Review Board**	**Approval Date:** **October 13, 2020**

PURPOSE

To set forth the requirements for obtaining informed consent from adults who are subjects in human research.

DEFINITIONS

Adult – a person who has attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private 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 means - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Vulnerable population – groups vulnerable to coercion, including children, individuals with impaired decision-making capacity, prisoners, and economically or educationally impaired individuals. Studies involving children should follow the NEIU Assent and Parental Permission SOP.

POLICY

Before a human subject participates in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject. Informed consent is an agreement by an individual who is competent and of legal age to participate in research. Consent is typically obtained by written signature. For web-based research, consent can be obtained by requiring participants to respond to a survey question affirming their consent to participate.

Vulnerable populations require additional protections when they are prospective research subjects. These protections are outlined in 45 CFR part 46, Subpart B for pregnant women, and Subpart C for prisoners. Studies involving children should follow the NEIU Assent and Parental Permission SOP.

Any consent information that is given to the subject shall be in language understandable to the subject and written at an appropriate level, usually no higher than 8th grade reading level.

> No informed consent may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Informed Consent

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented to the prospective subject in a way that facilitates comprehension. After presenting consent, the researcher should ask a few questions regarding the research to evaluate the subject's understanding of the research. Possible questions include:

a. Name at least two things that you will be expected of you during the study.
b. Do you have to participate in this research? Or is it Ok to say, "No?"
c. If you want to drop out of this study, when can you do this?

Development of consent form. The NIEU IRB created Checklist assists researchers in developing a consent form that includes all the required elements listed below.

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
b. A description of any reasonably foreseeable risks or discomforts to the subject;
c. A description of any benefits to the subject or to others that may reasonably be expected from the research;
d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
h. A statement that participation is voluntary, refusal to participate will involve no penalty or

loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

i. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; and
j. The approximate number of subjects involved in the study.

Waiver or alteration of consent

The NEIU IRB may waive the requirement to obtain informed consent for research or alter consent to omit some or all of the elements of informed consent provided the IRB satisfies the following requirements:

a. The research involves no more than minimal risk to the subjects;
b. The research could not practicably be carried out without the requested waiver or alteration (e.g., full disclosure of the purpose of the research would bias the results and render the outcomes of the research useless);
c. If the research involves using identifiable private information, the research could not practicably be carried out without using such information in an identifiable format;
d. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
e. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Passive Consent

If a researcher wishes to analyze data collected for other purposes (e.g., education records) with minimal risk to the subject, the researcher may obtain passive consent by contacting all prospective subjects stating the source of the data, the purpose of the study, and contact information of the researcher. If prospective subjects do not want the researcher to use their data, the subjects must contact the researcher directly to inform him/her of noncompliance. No contact establishes passive consent and allows the researcher to use the data.

PROCEDURES

1. The PI submits an IRB application which includes a proposed informed consent procedure and written forms prior to initiation of research.

2. The IRB application must indicate which study personnel will participate in the informed consent procedure or individuals the researcher will authorize to obtain informed consent n on his/her behalf.

3. The NEIU IRB provides an Informed Consent template, available on the IRB website. Investigators should use the template unless the IRB grants exemption or a waiver.

4. The IRB will assess the PI's description of the informed consent process to ensure that the process meets the general requirements of informed consent (i.e., consent be obtained from the subject; be in language understandable to the subject; be obtained under circumstances that allow the subject to adequately consider whether or not to participate; be obtained under circumstances that minimize coercion or undue influence; and does not include language through which the subject is made to waive his/her legal rights or releases the investigator, sponsor, or institution from liability for negligence).

5. The IRB is responsible for reviewing the proposed informed consent document(s) to ensure that all applicable federal and NEIU requirements are met.

6. Investigators may only enroll subjects using informed consent forms, which have been approved by the IRB unless the IRB grants a waiver from the requirement for informed consent or documentation.

RESPONSIBILITIES

1. The IRB is responsible for reviewing the proposed informed consent document(s) to ensure that all applicable federal and NEIU requirements are met.
2. Investigators may only enroll subjects using informed consent forms, which have been approved by the IRB unless the IRB grants a waiver from the requirement for informed consent or documentation.

Regulations

45 CFR 46 109(b)
45 CFR 46 111(b)
45 CFR 46 116
45 CRF 46 117

Author Reference

NEIU IRB

UIC Informed Consent Process and Documentation

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.