



IRB Standard Operating Procedures		
SOP#: 001 Revision#:	Title: External Research	Effective Date: December 10, 2019
Approved by:	Institutional Review Board	Approval Date: December 10, 2019

PURPOSE

To establish a standard method of reviewing and approving research conducted by external researchers that invites NEIU faculty, staff, students, or facilities as recruitment sites or uses data from NEIU that is not publicly available. This SOP does not cover NEIU faculty, staff, or student who are collaborators with external researchers.

DEFINITIONS

Engaged in Human Subjects Research - for the purposes of this policy, an institution is considered *engaged* in a human subjects research project when its employees or agents for the purposes of the research project actively recruit subjects or obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

Employees or agents - individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

External investigator – a researcher not affiliated with NEIU.

External research – a research project conducted by an investigator not affiliated with NEIU.

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 or identifiable biospecimens.

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.

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

POLICY

It is the policy of the NEIU IRB that all requests from external researchers to (i) recruit participants on the NEIU campus via poster, flyer, email announcement, newspaper ad, or any other method of recruitment, (ii) contact NEIU alumni, (iii) use NEIU facilities, and/or (iv) receive data from NEIU for research purposes must be reviewed by the NEIU IRB for appropriateness and compliance. Violations of this policy will result in a stoppage of research activities, notification of the PI's home IRB, and any other sanctions that the University deems appropriate.

Permission to conduct research at NEIU must also be obtained from the Institutional Official (Provost) and appropriate departments and/or units on campus. Permission will be granted on a case- by- case basis, but the researcher must provide a compelling justification for using University faculty, staff and students as study participants.

The NEIU IRB will apply the federal rules of [engagement of institutions in human subjects research](#) to determine the appropriate review procedure for the research.

PROCEDURES

Approval to solicit Northeastern Illinois University faculty, staff and students involvement in research conducted by external researchers must be obtained by the University IRB Chair prior to recruitment. Approval decisions are made on a case-by-case basis, but the researcher **MUST** provide a compelling justification to IRB for using University faculty, staff and students as study participants and/or demonstrate some direct benefits to the campus community. The IRB's expectation is that all requests will be forwarded to the IRB for a determination of how to proceed.

In order for the University IRB to consider such a request, the researcher must provide to the IRB:

- Approved and complete IRB protocol packet including consent forms from their home institution,
- Proof of training (i.e. CITI training certificate), and
- Complete an External Researcher Authorization Agreement

Approval Process:

1. The process begins when the IRB receives notice that an external researcher is planning to conduct human subject research at NEIU.
2. IRB staff request from the external researcher evidence of IRB approval or an exemption determination from the external researcher's IRB and all supporting documentation, including application, consent document, if applicable, and all documents subjects will receive or review.
3. IRB staff forward the request and associated documents to the IRB chair for review.
4. The chair will review the request and associated documents and determine whether the research is acceptable and may proceed at NEIU.
5. The external investigator will be notified about the chair's determination by email.
6. Assuming a positive determination, the chair and IRB staff will facilitate the process of obtaining permission from the Institutional Official (Provost) and appropriate departments and/or units on campus.
7. Copies of the correspondence, protocol, consent and other documents and IRB approval or exemption determination will be maintained in a folder labeled "External Researchers."

Regulations

[Engagement of Institutions in Human Subjects Research \(2008\)](#)

Author Reference

NEIU IRB

UC Davis IRB SOP "External Researchers Conducting Human Subject Research at UC Davis"

St. Mary's University IRB SOP External Researcher Guidelines

University of North Carolina Asheville SOP for External Researchers

Related Policies

Cooperative Research and Ceding of Review

Contact Information

Please direct questions or concerns about this policy to:

Contact

IRB Office

Dean of the College of

Graduate Studies and Research

Phone

773-442-4675

773-442-6012

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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.