



External Research Requests		
SOP#: 18 Revision#: 2	Title: External Researcher	Effective Date: February 23, 2021
Approved by:	Institutional Review Board	Approval Date: February 23, 2021

PURPOSE

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

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

Human subject - a living individual about whom a researcher (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.

Individual Investigator Agreements (IIA)- are used for External Investigators that are engaging in research on their own behalf, rather than on the behalf of an institution. These agreements typically apply to individuals without an affiliation to any institution, or those affiliated to organizations that do not have their own IRB (such as employees of small clinics).

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 with the federal guidelines. 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 and/or demonstrate some direct benefit to the campus community.

It is the responsibility of external researchers to secure all necessary letters of support from the offices/departments from which they intend to recruit their subjects. For research at NEIU, the external researchers must obtain the permission of the NEIU Institutional Official (Provost). The external researcher's IRB application and approval must demonstrate the letters of support have been reviewed and approved by the external researcher's home IRB.

The NEIU IRB will review for compliance of the research with regards to: 1) recruiting participants on the NEIU campus via poster, flyer, email announcement, newspaper ad, or any other method of recruitment; 2) contacting NEIU alumni; 3) using NEIU facilities; and/or 4) receiving data from NEIU for research purposes. The NEIU IRB consults based on anticipated risks and benefits and the protections afforded to the subjects. The NEIU IRB will be consulted by the Institutional Official about the appropriateness of the research requests and to help form a final decision regarding permission.

Violations of this policy will result in the Institutional Official mandating an immediate stoppage of research activities, notification of the PI's home IRB, and any other sanctions that the University deems appropriate.

If the external researcher's institution does not have its own IRB, an Individual Investigator Agreement (IIA) is required which will begin the NEIU IRB review process. For information regarding IIA procedure please see the NEIU IRB website.

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

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. All of the following documents must be submitted to the IRB office:
 - a. IRB approval letter from their home institution,
 - b. Letters of support (if determined necessary)
 - c. IRB application from their home institution,
 - d. Proof of training (i.e. CITI training certificate),
 - e. All recruitment materials, and
 - f. A complete Individual Investigator Agreement (IIA- when applicable).
3. IRB staff forwards the request and associated documents to the IRB chair for review.
4. After consultation with the IRB members, the IRB staff will notify the Institutional Official on the board's recommendations.
5. The Institutional Official will communicate the final decision to the IRB chair.
6. The IRB chair will notify the external researchers about the decision.

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

Phone

773-442-4675

E-Mail

irb@neiu.edu

Dean of the College of
Graduate Studies and Research

773-442-6012

gradstudies@neu.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.