IRB Standard Operating Procedures		
SOP#: 21 Revision#:	Title: NEIU IRB Authorization Agreement Process	Effective Date: March 14, 2022
Approved By:	Institutional Review Board	Approval Date: March 14, 2022

PURPOSE

This SOP provides guidelines for the Authorization Agreement Process. An Authorization Agreement may be used under certain circumstances to document the ceding of IRB oversight to a particular IRB when a human subject study has external collaborators engaged in the conduct of research. the This practice is commonly referred to as a ceded review, Reliance Agreement, or deferral of IRB oversight. At NEIU, the IRB refers to this as a ceded review.

When working with external collaborators, NEIU IRB has regulatory oversight responsibility for the human subject research activities of NEIU faculty, students, and staff. The research activity of an external collaborator engaged in a NEIU human subjects study must also be reviewed by either the IRB at the collaborator's institution or the NEIU IRB.

An Authorization Agreement may be established between the parties to cede regulatory oversight to one of the IRBs as the IRB-of-Record. The same process may be used when a NEIU investigator engages in human subjects research as an external collaborator.

DEFINITIONS

Authorization Agreement – (AA) identifies and describes the respective authorities, roles, responsibilities, and methods of communication between an

NEIU IRB will perform routine post-approval monitoring activities or conduct(for cause) reviews of study records. These oversight activities may be accomplished remotely, in collaboration with the IRB of Record. .
It is the policy of NEIU IRB that the NEIU PI will follow written procedures for reporting its findings and actions to the appropriate officials at the IRB of Record as noted in this policy 'Responsibilities'.
It is the policy of the NEIU IRB that, by signing the IAA and ceding review to the IRB- of- Record, the IRB of Record will follow written procedures for the conduct, reporting, and communication as noted in the policy 'Responsibilities'.

IRB Agreement Types:

1. IRB Authorization Agreement

   An IAA is an agreement between NEIU and another institution that holds a Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP) of the U.S. Department of Health and Human Services (HHS). Any institution (e.g. university, medical centers, community agencies, clinics) receiving funds from HHS must have an FWA. This agreement type is used to establish the IRB-of-Record (either NEIU or the other qualified institution). The IAA is signed by the Institutional Officials at each institution.

2. Individual Investigator Agreement (IIA)

   An IIA is an agreement between NEIU and an individual collaborator who is not affiliated with an FWA institution (e.g. former student, professional in the

Complying with all submission and reporting requirements of the IRB of Record.

Not engaging in human subjects research until a signed IAA has been established.

Complying with NEIU SOPs; applicable local, state and federal regulations; and regulations of the IRB of Record.

Ensuring safe and appropriate performance of research including, but not limited to monitoring protocol compliance, ensuring all collaborators and study staff are appropriately qualified, have completed CITI training and have been adequately trained to conduct the study in alignment with the IRB approved protocol.

Providing a mechanism to receive and address concerns from local study subjects and others about the conduct of research.

Promptly submitting reportable events to the IRB of Record.

Maintaining all IRB of Record's documentation and sharing this documentation with the NEIU iRB.

Responsibilities of the IRB-of-Record include, but are not limited to:

Conducting review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research.

Conducting review of potential unanticipated problems, adverse events, and/or serious or continuing non-compliance.

Providing notification to the PI in writing of its determinations and decisions.

Making relevant IRB minutes, IRB membership rosters, and standard operating procedures available to the NEIU IRB upon request.

When appropriate, conducting on-site or remote post-approval monitoring or audits, unless delegated to NEIU IRB.

Maintaining an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21 CFR 56.107 and which provides special expertise as needed to adequately assess all aspects of each study.

Promptly notifying the NEIU IRB if there is a suspension or termination of the External IRB's authorization to review a study.

Providing the NEIU IRB the contact person and contact information for the Reviewing IRB.

Maintaining appropriate documentation per record retention policies, including an OHRP-approved Federalwide Assurance (non-commercial IRBs) for human subject research.

Reporting to Sponsor, Federal Agencies, or Other Oversight Entities: If the IRB of Record determines that it must report information to the Sponsor, OHRP, the FDA and/or other oversight entities, it will notify the NEIU IRB within a reasonable time in advance of reporting.

The IRB of Record will share the report with NEIU IRB before it is sent to the sponsor/oversight authority, and will copy NEIU IRB official(s) and designees.

Procedures

NEIU PI must submit to NEIU IRB an electronic request to cede upon approval of the IRB of Record.

NEIU PI must submit IRB of Record approval and all submitted documents including but not limited to approved protocol, consent documents, recruitment flyers, instruments, surveys, etc.

NEIU IRB makes a determination after review of the PI's ceding request, documents and IRB of Record's approval.

NEIU PI is notified via email regarding the determination

Post Approval Reporting

After NEIU IRB has approved the reliance on IRB of Record , the following must be reported to NEIU IRB

Data and safety monitoring plans and reports, when applicable

Reportable events

Protocol violations

Reports of serious or continuing noncompliance

Unanticipated problems involving risks to human subjects

Termination of the IAA

Either the NEIU IRB or IRB of Record may unilaterally terminate the acknowledgement by providing thirty (30) days notice to the NEIU PI.

Regulations

45 CFR 46.102

Author Reference

NEIU IRB
George Mason University SOP “Classroom Projects”
University of Michigan Research Ethics & Compliance
HRP-102- SOP- NASA IRB Reliance on an IRB of Record

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.