



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

## **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. 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 institution/organization providing the ethical review of research and a participating site relying on the institution/organization.

**Axiom Mentor IRB-** is an online software solution for research compliance submission, review and reporting platform used by NEIU PI and NEIU IRB. Investigators use this online platform to submit and track all their human subjects research protocols. The NEIU IRB utilizes the platform for protocol review, determination and approval.

**Central IRB (CIRB)/Single IRB (sIRB)** – the selected IRB of record that conducts the ethical review of research for all participating sites of a multi-site study.

**Federalwide Assurance (FWA)** - a formal, written, binding attestation in which an institution ensures to the U.S. Department of Health and Human Services (HHS) that it will comply with applicable regulations governing the protection of human subjects.

**IRB Authorization Agreement (IAA)** - 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). NEIU IRB utilizes this agreement type to establish which institution will serve as the IRB of Record. Each institution's Institutional Official or designee signs the IAA. The IAA is an agreement entered into by two or more institutions engaged in human subject research that permits one or more institutions to cede IRB review to another IRB. The signed IAA acknowledgement permits a single IRB to review human subject research activities for more than one site and documents respective authorities, roles, responsibilities, and communication between an organization providing the ethical review and a participating organization relying on a reviewing IRB.

**IRB of Record** (alternatively referred to as the Reviewing IRB) - an IRB that assumes IRB responsibilities for another institution or independent investigator for a specific study, group of studies, or for all research conducted by the other institution/investigator.

**Individual Investigator Agreement (IIA)** – the agreement of an individual investigator (also referred to as research study personnel) to Institutional Human Subject Protection Policies and IRB Oversight, particularly those outlined by the institution which extends its Federalwide Assurance to cover the individual investigator under specified research protocols.

**Institutional Official (IO)** - the signatory on the FWA filed with the Office for Human Research Protections (OHRP). OHRP requires the IO to be a high-level official who has the authority to represent the institution named in the FWA. The VPR serves as the IO for NEIU and is responsible for signing IAAs and Individual Investigator Agreements (IIAs) on behalf of the institution.

**Multi-site/collaborative/cooperative research study** – non-exempt human subjects research conducted at more than one site.

**Principal Investigator (PI)** - the study's lead investigator at NEIU responsible for the preparation, conduct, and administration of the proposed research.

**Relying IRB or Organization** – is relying on the review of or has ceded IRB review to the IRB of Record for the oversight for a specific research study or set of studies.

**Reviewing IRB** – (alternatively referred to as the IRB of Record) The IRB that provides the ethical and regulatory review of the research.

## **POLICY**

NEIU investigators should not initiate an Authorization Agreement with another institution without first checking with the NEIU IRB to :

- Verify that the collaborator's research activity meets the definition of "engaged" in research
- Identify the appropriate type of IRB agreement
- Facilitate the signing of the agreement by the NEIU Institutional Official, as applicable
- Implement and manage the agreement

NEIU considers to rely on an External IRB when federally mandated, required by sponsors, or on a case-by-case basis.

- It is the policy of the NEIU IRB that NEIU PIs may rely upon another institution's IRB (IRB of Record) for human subjects research approval, review, and oversight. This reliance requires the approval of NEIU IRB.
- NEIU IRB and other organization(s) participating in research agree to rely on one specified institution (IRB of Record) for research approval, review, and oversight
- NEIU IRB must approve the IRB Authorization Agreement (IAA) before any engagement in human subjects research begins.
- Prior to engagement in human subjects research under another IRB, the NEIU IRB must receive the IRB submission and all accompanying documents (protocol, consent documents, instruments/surveys, flyers, recruitment script, etc.) that have been approved to the other IRB (IRB of Record) in order to approve the ceding.

- 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 community, community partners). This agreement type outlines the responsibilities of the individual investigator for the protection of human subjects.

The IIA is signed by:

- Individual investigator
- NEIU Principal Investigator (PI)
- NEIU Institutional Official (federally-sponsored projects), or IRB Chair for all others

### **RESPONSIBILITIES**

Responsibilities of NEIU Principal Investigator include, but are not limited to:

- Obtaining all required and applicable NEIU departmental, college, office approvals as necessary and include the information in the study submission.

- 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	<a href="mailto:irb@neiu.edu">irb@neiu.edu</a>
Dean of the College of Graduate Studies and Research	773-442-6012	<a href="mailto:gradstudies@neiu.edu">gradstudies@neiu.edu</a>

### 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.