



IRB Standard Operating Procedure		
SOP#: 04 Revision#: 1	Title: IRB Membership	Effective Date: March 09, 2018
Approved By:	Institutional Review Board	Approval Date: March 09, 2018

PURPOSE

To outline the composition and responsibilities of the IRB and establish the processes for selecting, appointing, and evaluating the members of the IRB.

DEFINITIONS

Affiliated Member - an employee or nonemployee of NEIU who has a formal or informal relationship with NEIU is considered affiliated. An unaffiliated member has no close formal or informal association with NEIU, other than as an IRB member.

Institutional Official (IO) - a high-level official within NEIU’s administrative team who has the authority to represent the institution named on a Federalwide Assurance (FWA), as well as the institutional components listed in the FWA. The individual should be at a level of responsibility that would allow authorization of necessary administrative or legal action should that be required. Also referred to as the “signatory official.”

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.

Prisoner Representative - an IRB member who has a close working knowledge, understanding and appreciation of conditions from the perspective of prisoners. The prisoner representative cannot be an employee of a correctional facility.

Scientist/Nonscientist - all IRB members are categorized as “scientist” or “non-scientist”. Scientist: Members will be considered “scientists” when the preponderance and recency of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a researcher. Nonscientist: Members will be considered “nonscientists” when the preponderance and recency of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a lay person.

1. COMPOSITION, QUALIFICATIONS, AND DIVERSITY

1.1. IRB Members

- 1.1.1. The IRB has a minimum of five members with varying backgrounds to adequately review the research activities commonly conducted at NEIU.
- 1.1.2. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Also, the IRB consists of at least one member who is not otherwise affiliated with NEIU and is not part of the immediate family of a person who is affiliated with NEIU.
- 1.1.3. To enable the IRB to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice, the IRB includes persons knowledgeable in these areas and may include representatives of administration.
- 1.1.4. The IRB is sufficiently qualified through the experience, expertise, and diversity of its members – including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes – to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- 1.1.5. Because the IRB may review research that involves a vulnerable category of subjects, the IRB may include – either as members or consultants, as appropriate – individuals who are knowledgeable about, and experienced in, working with these categories of subjects.
- 1.1.6. The IRB supports the principles of equal opportunity in employment and education. The IRB does not discriminate on the basis of race, color, religion, sex, pregnancy, disability, national origin, citizenship status, ancestry, age, order of protection status, genetic information, marital status, sexual orientation, gender identity, gender expression, arrest record status, military status, or unfavorable discharge from military service when selecting IRB members.

1.2. IRB Chair

- 1.2.1. The chair is selected from among the tenured faculty of the Institution. The chair must have previously served as a member of the NEIU IRB.

1.3. IRB Vice Chair

- 1.3.1. The vice chair is selected from among the tenured faculty at the Institution. The vice chair must have previously served as a member of the NEIU IRB.

1.4. Ex-Officio Members

- 1.4.1. The IRB may include non-voting ex-officio members, depending on the relevance of their office, expertise, and experience.

1.5. Prisoner Representative

- 1.5.1. The prisoner representative is listed on the IRB membership roster as a voting member, with the stipulation in the “Comments” section that the representative will only count towards quorum when s/he is in attendance and reviewing prisoner research studies.

1.6. IRB Consultants

- 1.6.1. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that available on the IRB. These consultants are not counted as IRB members in establishing the numerical quorum for each IRB, and may not vote with the IRB.

2. SELECTION, APPOINTMENT, AND LENGTH OF SERVICE

2.1. IRB Members

- 2.1.1. Candidates for IRB membership may be nominated by the IRB chair, the deans, IRB staff, faculty, or academic departments. They may also be self-nominated. Unaffiliated members are identified by interest and relevance, and are recommended for appointment by members of the IRB, IRB staff, deans, faculty, and academic departments.
- 2.1.2. The formal appointment of IRB members is made by the Institutional Official. The Dean of the College of Graduate Studies and Research, with input from the various university constituencies, will choose and forward nominees to the Institutional Official for any additional review and formal appointment.
- 2.1.3. The IRB member nomination packet must minimally include: a copy of the nominee's resume or curriculum vitae. An appointment is considered effective at the time and date when the appointment letter is signed by the Institutional Official.
- 2.1.4. IRB members are appointed to membership slots of 3-year terms that align with the start of each academic year. Appointments are renewable by mutual agreement.
- 2.1.5. Appointments end if they are not renewed after the 3-year appointment. Non-renewal does not preclude from future services on the IRB.
- 2.1.6. Members may end their appointment before completion of the 3-year term by notifying the IRB chair in writing.

2.2. IRB Chair

- 2.2.1. The IRB chair is selected based on experience with, and knowledge of, applicable federal regulations, state laws, and institutional policies.
- 2.2.2. The IRB chair is nominated by and voted for by IRB members. The Dean of the College of Graduate Studies and Research will communicate the IRB's recommendation to the Institutional Official, who makes the formal appointment with input from the various university constituencies.
- 2.2.3. The IRB chair is appointed to a three-year term that aligns with the start of the academic year. Appointments are renewable by mutual agreement with the Institutional Official.

2.3. IRB Vice Chair

- 2.3.1. The IRB vice chair is selected among tenured faculty based on experience with, and knowledge of, applicable federal regulations, state laws, and institutional policies.
- 2.3.2. The IRB vice chair is nominated by and voted for by IRB members. The Dean of the College of Graduate Studies and Research will communicate the IRB's recommendation to the Institutional Official, who makes the formal appointment with input from the various university constituencies.
- 2.3.3. The term of appointment of the vice chair will be aligned with that member's term of appointment.
- 2.3.4. Refer to "Administrative Supplement" for procedural details.

3. RESPONSIBILITIES

3.1. IRB Members

- 3.1.1. Review IRB applications, including informed consent, questionnaires, and recruitment documents, to ensure that applications include adequate protections for human research subjects in the research plan.

- 3.1.2. Participate in full board reviews.
- 3.1.3. Attend IRB monthly meetings. Two unexcused absences per academic year are grounds for replacement.
- 3.1.4. At least once a year, attend a formal educational event pertinent to the oversight of human subjects research (such as web-based training, guest speakers, or conferences), in addition to any educational sessions presented during convened IRB meetings.
- 3.1.5. Follow the Conflict of Interest SOP.
- 3.1.6. Maintain confidentiality for all discussions, reviews, meeting minutes, and other information encountered as a member of the IRB.

3.2. IRB Chair

- 3.2.3. Share the responsibilities of all IRB members.
- 3.2.4. Determine the type of IRB review required (*exempt, expedited, full board*) based on official regulatory criteria. The chair may delegate this task to qualified IRB staff members.
- 3.2.5. Review all *expedited* studies. The chair may delegate this task to the Vice Chair or another IRB member.
- 3.2.6. Convene and chair the meetings of the IRB.
- 3.2.7. Review amendments to expedited studies, except for changes in personnel, performance sites, and funding that do not affect the study's expedited status. The chair may delegate this task to the vice chair or another IRB member.
- 3.2.8. Sign approval memos.
- 3.2.9. Review reports of unanticipated problems.
- 3.2.10. Participate in investigations of non-compliance.
- 3.2.11. Make recommendations to the IRB about suspension or termination of research studies based on the results of investigation of noncompliance.
- 3.2.12. Conduct evaluations of IRB members at the end of their 3-year term.
- 3.2.13. In addition, the chair serves as a resource for investigators and IRB members regarding issues and policies related to human subjects protection.

3.3. IRB Vice Chair

- 3.3.3. The IRB vice chair assists the chair in the chair's responsibilities and assumes the responsibilities and obligations of the Chair when the Chair is unable to serve in that capacity, or when the chair is an investigator on a research project being considered or reviewed by the IRB. The duties and responsibilities of the vice chair are the same as for any IRB member except when assuming the role of the chair.

4. TRAINING

4.1. IRB Members, IRB Chair, and Vice Chair

- 4.1.1. All IRB members are required to complete all relevant training in human subjects protection and maintain the currency of their training.

5. EVALUATION

5.1. IRB Members, IRB Chair, and Vice Chair

- 5.1.1. All IRB members will be informally evaluated by the IRB chair and the Dean of the College of Graduate Studies and Research at the end of their 3-year term. The IRB chair and vice chair will be informally evaluated annually by the Dean of the College of Graduate Studies and Research and the Institutional Official.
- 5.1.2. Evaluations will consider the following criteria:
 - Knowledge and application of federal regulations and ethical principles
 - Knowledge and application of IRB policies and procedures
 - Completion of required member training
 - Meeting attendance
 - Review of IRB applications (quality / quantity / timeliness)
 - Participation in educational sessions
 - Constructive participation in IRB discussion
- 5.1.3. An IRB member who is not adequately fulfilling the standards and responsibilities listed above may be recommended to the Institutional Official for additional training or the termination of appointment.

6. IRB MEMBER CONFLICT OF INTEREST

- 6.1. IRB member conflicts of interest are defined and handled as described in the SOP "IRB Member Conflict of Interest."

7. IRB STAFF

- 7.1. The IRB staff member assists the chair and vice chair in IRB activities. The support staff is responsible for assisting researchers in the application process, facilitating review of submitted applications, preparing IRB meetings, documenting meeting minutes, assisting with IRB policy development, planning and conducting campus wide educational events at least once a year and performing other tasks in support of the IRB operations.
- 7.2. IRB staff member is required to maintaining currency in CITI training and be familiar with federal, state, and local regulations, and institutional policies and procedures.
- 7.3. IRB staff will be evaluated formally by the supervisor following established HR procedures and informally by the IRB chair.

Regulations

45 CFR 46.107

21 CFR 56.107

Author Reference

NEIU IRB

Contact Information

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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.