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IRB Membership and Responsibilities

Purpose

Northern Illinois University is responsible for developing a review body that will review and approve research carried with human participants. This policy is intended to clarify how the members of that review body are determined and what their responsibilities are.

Policy Narrative

RESPONSIBILITIES OF THE IRB

All research activities involving human subjects which are sponsored by Northern Illinois University (NIU) or are conducted by or under the direction of any employee or agent of the university in connection with his/her university responsibilities are subject to Institutional Review Board (IRB) review.

The IRB establishes and implements policies and procedures for the review of research involving human subjects. These policies and procedures detail the mechanisms to be used for the initial review of newly proposed research protocols, the review of proposed amendments to previously- approved protocols, review of requests for continuation of approval, and the investigation of unexpected or adverse events (defined as harm to a subject not previously identified as a risk) and/or possible noncompliance by any person covered by this policy, including the suspension or termination of approved protocols and reporting to necessary federal offices/agencies.

The IRB reports directly to the Vice President for Research and Innovation Partnerships, who serves as the Institutional Official (IO) for the University.

RESPONSIBILITIES OF IRB MEMBERS

New IRB members are expected to participate in an orientation session with Office of Research Compliance, Integrity and Safety (ORCIS) staff before being eligible to sit as a voting member at a convened meeting and to complete one additional appropriate educational activity (e.g., attending a conference or workshop pertaining to human subjects research protection or completing the CITI online training for IRB members) during their first six months as IRB members.

IRB members are expected to attend all meetings unless they have a compelling reason to be absent and have notified the ORCIS staff of their pending absence. IRB members are expected to read all application materials provided before the scheduled meetings and to come to meetings prepared to discuss the applications.

IRB members agree to make themselves available, upon request, to consult with other members, ORCIS staff, and researchers on issues relevant to the review of specific protocols.

IRB MEMBERSHIP

The IRB will be made up of at least five individuals, one of whom must not be affiliated with the University in any way. The members must be of varied background, including consideration of the gender and racial and cultural backgrounds of members 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. The IRB members must also possess sufficient expertise to provide complete and adequate review of the types of human subjects research commonly conducted at NIU. The IRB shall include at least one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas.

The IRB membership is appointed by the IO. All NIU IRBs will include at least one member from each of the following categories:

Faculty member, Psychological Expertise

Faculty member, Educational Expertise

Faculty member, Physiological Expertise

Faculty member, Social Science Expertise

Non-Scientist

Community member (not affiliated with NIU)

Other IRB members may be recruited based on an assessment of need. Individuals internal or external to NIU may be recruited to serve as a consultant to the IRB when the IRB Chair or IRB administrator determines that expertise or knowledge not available within the IRB membership is needed to fully consider a specific research protocol. Such consultants may not vote on the protocol(s) and are not appointed to the IRB. Recruitment of IRB members and consultants may be performed by the IRB Chair, IRB members and staff, and NIU administrators such as Deans and Department Chairs as appropriate.

Members are appointed to three-year, renewable terms. When a member term is concluding, the IRB Chair and the IRB administrator, in consultation with the IO as needed, will evaluate whether or not reappointment should be offered. A reappointment offer is made based on the member's attendance, meeting preparation, and contribution to the IRB's work over the course of his/her membership as well as the anticipated needs of the IRB in the future.

The IO will appoint a Chair for each IRB. IRBs may also have one or more Vice Chairs who may serve as an alternate for the Chair when necessary. IRB Chairs are appointed for a three-year term and are subject to the same reappointment considerations described above for IRB members.

IRB RECORDS

The IRB, with the assistance of IRB administrative staff from ORCIS, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by research investigators (as part of continuing review or otherwise) and reports of unanticipated problems involving subjects.
2. Minutes of IRB meetings, which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the researchers.
5. A list of IRB members as required by 45 CFR 46.103(b)(3).
6. Written procedures for the IRB as required by 45 CFR 46.103(b)(4) and 45 CFR 46.116(b)(5)
7. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5).
8. Official correspondence with the Office of Human Research Protections (OHRP).

The IRB shall provide for the maintenance of records relating to a specific research activity for at least three years after termination of the last IRB approval period for the activity. IRB records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services (HHS) at reasonable times and in a reasonable manner or shall be copied and forwarded to HHS when requested by authorized HHS representatives. Researchers are encouraged to retain personal copies of their applications, correspondence, etc. as well. Changes in IRB membership shall be reported to the OHRP at least annually.

AMENDMENT OF IRB POLICY AND PROCEDURES

Amendment of policy and procedures may be recommended at any time by the IRB. Proposed amendments shall be submitted to the full board for review and must be approved by a majority of a convened meeting or by written vote following sufficient opportunity for questions and discussion. Approved amendments shall then be forwarded to the IO for review and final approval.

Procedural History of the Policy

Approved by the convened Institutional Review Board and the VP for Research in January 2021.