

IRB MEMBERSHIP POLICIES AND PROCEDURES

Membership Requirements (as mandated by federal regulations):

- At least six members, both genders
- Varied professions including scientific background (enough for appropriate expertise)
- At least one member whose primary expertise is in a non-scientific area
- One member otherwise not affiliated with the university and who is not a part of the immediate family of a person affiliated with the university
- Experience, expertise, diversity
- Sensitivity to community attitudes
- Knowledge of institutional commitments and regulations, applicable law, standards of professional conduct
- When research is reviewed involving a category of vulnerable subjects (for example, prisoners, children, individuals institutionalized as mentally disabled) the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects

Board Composition:

1. UNK's IRB will include a minimum of 6 and no more than 12 voting representatives to include:
 - **At least 1 representative from the College of Business and Technology**
 - **At least 1 representative from the College of Education**
 - **At least 1 representative from the College of Arts and Sciences**
 - **At least 1 UNK staff representative**
 - **At least 1 community representative (cannot be affiliated with UNK/not a family member or spouse of an employee or an active alumnus)**
 - **1 graduate student member (as available)**
 - **At least 1 representative from a Social Scientific background**
 - **At least 1 member should be a medical practitioner (this person may represent a broad range of medical-related expertise/desirable to involve a representative from the nursing program)**
 - **At least 1 member whose primary interests are in a scientific area**
 - **At least 1 member whose primary interests are in a non-scientific area**
 - **Only 1 member per academic department at any given time**

Board members may serve dual functions; for example the community representative may also be a medical practitioner. Or the non-scientist non-affiliated person may be the same individual. (See Appendix A for the list of current IRB members and their terms.)

- **Non-voting Ex Officio Members:**

The director of the IRB and a representative from the Division of Research hold the positions of *ex officio* members of the Board. *Ex officio* members do not have voting privileges. Their terms are indefinite and are filled by the person in the respective position.

- **Community Members:**

Federal law requires that the IRB have at least one member not affiliated with the university and who is sensitive to community attitudes and issues.

- **Consultants Option:**

The director, at their discretion, may invite individuals with competence in a particular area to assist in a review if a research proposal poses particularly complex issues or requires expertise beyond or in addition to that routinely available on the IRB. Suggested consultants can be submitted to the director by the chair or other board members. Consultants may attend the IRB meeting; however, they will not count toward quorum. Neither can consultants vote on approval. Consultants participating in Board meetings will sign the confidentiality/conflict of interest agreement. Consultants will need to be CITI trained.

Membership Appointment Policy

- **Board Appointments:**

1. IRB members shall be appointed by the Assistant Vice Chancellor for Research (or designated Institutional Official), who shall consult with the IRB Director and Chair, and may consult with other Board members, college deans, and/or the SVCASA.
2. Community members (who are unaffiliated with UNK) may be nominated by current members of the IRB, the UNK community, or by community leaders knowledgeable about the qualifications of the nominee and the requirements of IRB service. Community membership appointments will be approved by the Assistant Vice Chancellor for Research.

- **Membership Qualifications:**

Membership is based on the expertise and experience relative to the types of research being reviewed by the IRB.

- **Vacancy Appointments:**

Vacancies will be filled by individual(s) having the appropriate expertise and experience relative to the types of research being reviewed by the IRB as well as the composition needs of the Board.

1. When a vacancy occurs on the IRB, the director will notify the Assistant Vice Chancellor for Research, who may select a candidate. The Assistant Vice Chancellor for Research shall consult with the IRB Director and Chair, and may consult with other Board members, college deans, and/or the SVCASA.
2. Nominations to fill Board vacancies may also be made by members of the IRB and the UNK community including faculty and administrators.
3. Nominees will be contacted by the IRB director in order to provide information about the role of the IRB, policy and procedures, the duties and expectations of Board members.

4. Nominees interested in a Board appointment will contact the IRB director and provide a current curriculum vitae along with a letter stating their interest in serving on the IRB within one month of nomination.
5. The IRB director and chair may review the nominees' credentials and recommend the vacancy appointment(s) to the Assistant Vice Chancellor for Research.
6. A community and/or medical member vacancy can be filled upon recommendation by current members of the IRB, the UNK community, or by community leaders knowledgeable about the qualifications of the nominee and the requirements of IRB service. The same procedure for other vacancy appointments will be followed.
7. All candidates for a vacancy appointment will be approved and officially appointed by the Assistant Vice Chancellor for Research.
8. A letter from the Assistant Vice Chancellor for Research will be sent to each new member to confirm the appointment.
9. New members must complete the CITI training within one month after appointment. New Board members failing to complete the requisite training cannot serve on the Board.

Credentialing of IRB Membership:

Nominees should submit to the IRB director and chair a curriculum vitae or résumé, and/or other materials to document their technical areas of expertise, along with a letter affirming interest in serving on the Board and availability to review protocols and participate in meetings.

The IRB director and chair will review the documents to identify those nominees with the expertise/qualifications to review the types of research commonly presented to the Board. Their recommendation for appointment will be forwarded to the Assistant Vice Chancellor for Research.

The IRB retains nomination documents and CITI training records in a permanent membership records file.

The following documentation is required from each Board member at initial appointment and/or re-appointment:

- Current curriculum vitae
- Documentation of the requisite CITI training and refresher courses

• Membership Training Requirement:

Board members must complete the training prior to reviewing or voting on any research. New members should complete the training within one month after appointment. New Board members failing to complete the requisite training and current Board members failing to complete the refresher course cannot serve on the Board. The online CITI training programs to be completed are:

- Module for IRB Members Only
- Depending on the research area, select either the Faculty Social and Behavioral Research or the Faculty Biomedical Research training programs

Board members are encouraged to complete optional modules particularly if a research proposal involves as subjects children or prisoners; comprises culturally diverse subjects; is international; or examines documents and records.

- **Board Terms:**

Appointments are for one 3-year term and renewable by mutual agreement of the Assistant Vice Chancellor for Research and the IRB director based on needs of the IRB and an annual performance review.

- **Annual Review of Board Composition and Board Performance Reviews:**

1. Board composition is reviewed at least annually by the Assistant Vice Chancellor for Research, and the IRB director to determine appropriate Board membership composition in terms of regulatory and current campus research requirements. Board composition should follow a similar review process as vacancies on the Board occur.
2. The IRB director with input from the chair, vice chair, and staff annually evaluates individual Board member performance in terms of attendance, timeliness, and review quality. Feedback to individual members is provided by the director.
3. Board members annually review the performance of the chair and vice chair.

Roles and Responsibilities:

The IRB director, chair, vice chair, and members serve to ensure that the rights and welfare of human subjects participating in research are protected under federally-mandated ethical principles.

The director, chair, vice chair, and members are required to maintain confidentiality of IRB-related information as designated by the terms and conditions of the IRB confidentiality/conflict of interest agreement.

The director, chair, vice chair, and members are expected to fulfill their duties to the IRB in accordance with the “Standards of Professional Conduct” as prescribed by the University of Nebraska Board of Regents and generally accepted as the professional rights and duties of the academic community.

The roles and responsibilities specific to the director, chairs, and members follow:

- **Director:**

The IRB director’s role is subsumed by the Associate Dean of Graduate Studies and Research and Acting Director of Research Compliance:

- Manage protocol reviews to include determining the level of review (exempt, expedited, or full-board).
- Review all exempt proposals, changes in protocol, and shared jurisdiction research.
- Serve as one reviewer for expedited protocols during the summer, if needed.

- Write all post-review correspondence including approval, change of protocol, and continuing review (annual update) letters, as well as letters explaining requisite modifications and/or information required for approval. If the IRB disapproves a protocol, the director provides the researchers with an explanation in the written correspondence.
- Provide assistance to researchers with protocol preparation.
- Present informational sessions about the IRB to classes, organizations, and orientation sessions.
- Report problems and update information to external and/or internal sources. (For example, researcher non-compliance is reported to the researcher's supervisor and to the Office for Human Research Protections (OHRP) in the event of serious or continuing non-compliance.)
- Keep current IRB membership changes to OHRP.

Chair:

The chair is appointed by the Assistant Vice Chancellor for Research and the IRB director with approval from a majority vote of the Board. Selection is based on both experience and expertise. The Chair serves a 1-year term with renewable terms by mutual agreement of the Assistant Vice Chancellor for Research and the IRB director.) Responsibilities of the chair are:

- Facilitates convened meetings.
- May serve as a reviewer for expedited reviews/may determine the need for a full-board review.
- Consults with the director, vice chair, and other Board members for resolution of controversial and/or procedural matters relating to research approval and conduct.
- Assists the director in advising and education.
- Provide assistance to researchers with protocol preparation.

Vice Chair:

The vice chair is appointed by the Assistant Vice Chancellor for Research and the IRB director with approval from a majority vote of the Board. Selection is based on both experience and expertise. The Vice Chair serves a 1-year term with renewable terms by mutual agreement of the Assistant Vice Chancellor for Research and the IRB director. Responsibilities of the vice chair are:

- Provide support for the IRB chair.
- Facilitate convened meetings in the absence of the chair.
- May serve as a reviewer for expedited reviews/may seek a full-board review after consultation with the chair and director.
- Assumes duties as delegated by the director.
- Provide assistance to researchers with protocol preparation.

Members:

Each member of the IRB is appointed for one 3-year term and renewable by mutual agreement of the Assistant Vice Chancellor for Research and the IRB director based on needs of the IRB and an annual performance review. Member responsibilities are:

- Complete the initial CITI training in human subjects protection with continuing education every three years.
- Attend all IRB full-board meetings and actively participate in the review and discussion of research. Meetings are scheduled the third Wednesday of the month at 8 a.m. in Warner Hall 2147. Notification of meetings will be provided at least one week in advance.
 - Prior to a meeting, the member must:
 - Be familiar with the protocol(s) being reviewed, and be prepared to recommend changes if necessary
 - Carefully review the consent form, and be prepared to recommend changes if necessary
 - If questions/concerns before voting endorsement of approved exempt, expedited protocols, changes in protocol, and shared jurisdiction projects, contact the director or administrative associate
- Demonstrate an understanding of the principles of the Belmont Report and the federal regulations related to the protection of human subjects.
- Serve as second (or third) reviewer on expedited protocols on a rotating basis. The director will designate the reviewer based on area of expertise.
- Serve as a primary and/or secondary reviewer for full-board reviews as designated by the IRB director.
- Provide assistance to researchers with protocol preparation.

Community Members:

In addition to the roles and responsibilities assumed by all Board members, community members:

- Provide the community perspective on research and the protection of human subjects.
- Function as a link among the IRB, the investigator, and the community to strengthen public trust in research.
- Provide insight when analyzing the informed consent document for clarity and understandability.

Removal from the Board and Temporary Leave of Absence:

A Board member failing to adequately perform his/her responsibilities may be removed from the Board following correspondence or a meeting with the director. If the IRB member indicates an inability to function effectively on the Board or a need for temporary absence from the Board, a replacement may be appointed to maintain appropriate Board membership composition. The vacancy appointment will be filled by the Assistant Vice Chancellor for Research (see vacancy appointment section). The replacement member may serve the remainder of the vacated term or on a temporary basis, depending on the circumstances. The new member is expected to complete CITI Training within one month of appointment and thereafter assume all roles and responsibilities of Board members.

Modifications to Policy and Procedures:

Routine modifications to IRB Policy and Procedures (for example, new contact names, position titles, or grammatical and format changes) can be submitted to the Assistant Vice Chancellor for Research, the IRB director, and/or the chair and vice chair for immediate correction. New procedures or substantive changes will follow a review and approval process among the Assistant Vice Chancellor for Research and the IRB director, who may consult with the chair, the vice chair, or other Board members.

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