Policy II1 Recruitment, Appointment, Terms and Evaluation of IRB Members and Chairs

Scope
This policy describes the recruitment, appointment, terms and evaluation of members and Chairs of the University of Nevada, Reno (the University) Institutional Review Boards (IRBs).

Policy Statement
All University IRBs shall maintain a membership that conforms with federal regulation 45 CFR 46 and, as appropriate, 21 CFR 56. Membership shall be appropriate in size and expertise to fulfill the IRB’s obligations to safeguard the rights and welfare of human research participants, and to conduct the scientific and ethical review of protocols, reflecting the nature of research under a given IRB’s purview. Recruitment, appointment and evaluation of IRB members and Chairs shall be conducted in a manner that supports the responsibilities of the IRB.

Reason for the Policy
The comprehensive review of human research required of the IRB necessitates multiple perspectives, scientific expertise, a firm grounding in ethical principles and legal and regulatory requirements, and knowledge of local context. Sound leadership is also required to ensure consistency in the application of ethical principles, University Human Research Protection policies and procedures, and to guarantee that the IRB fulfills its obligations pursuant to federal regulations. This policy helps to ensure that the University’s IRBs are led by and composed of individuals who have the knowledge and expertise to perform their critical roles.

Definitions

Institutional Review Boards
A group of University faculty and graduate students; VA representatives; OHRP Director and Program Managers; and community members who are qualified through training and education and who are responsible for review and oversight of biomedical or social behavioral human subjects research.

Institutional Official
A senior official named in the FWA who has the authority to commit the entire organization, as well as all of the components listed in the FWA, to a legally binding agreement. The Institutional Official (IO)
also has the authority to assure compliance of the organization and all of its components to the Terms of the FWA. At the University, the IO is the Vice President of Research.

**II1A Recruitment**
Members for each IRB will be recruited based on conformance with federal regulations and an assessment of need. The IRB will maintain diversity of membership, including race, gender, and sensitivity to community attitudes in order to fulfill its obligations to review the breadth of research that is conducted by investigators representing the University.

Additionally, an individual internal or external to the University or affiliate community may be recruited to serve as a consultant to the IRB when an IRB Chair or Program Manager, the Office of Human Research Protection (OHRP) Director determines that expertise or knowledge that is not available within the current IRB but is needed by the IRB to fully consider a specific research protocol.

The IRB may nominate candidates to the Director. Department chairs and others may forward nominations to the Vice President for Research (i.e., the Institutional Official), IRB Chair or the OHRP Director.

Recruitment of consultants is the responsibility of the IRB Chairs, OHRP Director, IRB members and IRB Program Managers, as appropriate.

Recruitment of Chairs is the responsibility of the IO, the OHRP Director or both.

**II1B Appointment and Terms**
Appointment to IRBs is made by the IO, OHRP Director or both. Members are appointed for a renewable three-year period. Reappointment to an IRB may occur when a member has successfully completed his or her term and wishes to remain on the IRB. Reappointment is made by the IO, OHRP Director or both based on the recommendation of the Chair, after assessing the member’s contribution over the course of the term and the current and future needs of the IRB. Reappointment terms are generally for the same duration as initial terms. Exceptions may be made, depending on individual circumstance and IRB need.

**II1C Evaluation of IRB Membership and Members**
With any change in membership, the IRB Chairs identify those members who may review protocols at convened meetings, those who may review protocols using expedited procedures and those who may serve as chairs in the chair’s absence. These determinations are based on members’ participation in meetings, understanding and knowledge of the requirements for approval of human subjects research, education and level of comfort in conducting reviews or serving as the chair. These determinations are documented in a letter of authorization.

Whenever a member leaves the IRB and at least annually, IRB Chairs and Director perform an assessment of the IRB. The assessment considers IRB composition, including alternate members, areas
of expertise, community representation and diversity. Decisions regarding future recruitment and education efforts are identified to ensure that membership and supplementary consultants possess the expertise and knowledge required for appropriate scientific and ethical review of research.

When a member’s term is concluding, the Chair and Director 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 her or his membership as well as the projected needs of the IRB in the coming term.

During the course of their term, each IRB member completes a self-evaluation assessing their understanding of regulations and policies, review and preparation of materials prior to meetings, participation in meeting discussion, interactions with investigators and IRB staff, and human research education during the previous year. This tool is reviewed by the IRB Chair or Vice Chair in a confidential meeting with the member. The self-assessment and attendant discussion is used to determine areas of focus, if needed, and decisions about continued membership.

Annually, each IRB member will complete an anonymous evaluation of the IRB Chair. The evaluations will be reviewed by the Director. Feedback will be given to the Chair by the Director and shared with the Vice President for Research. All evaluations will be kept anonymous and only de-identified data will be provided to the Chair to ensure member confidentiality.

**II1D Consultants**
Consultants may be sought to aid the IRB in the review of specific protocols that require expertise beyond the scope of IRB membership. Consultants do not have appointed terms, as their participation is limited to the review of specific protocols. Consultants may not vote with the IRB membership.

**II1E Resignations and Removals**
A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. A member may be removed by the Vice President for Research upon recommendation of the IRB. Grounds for removal include not acting in accordance with the IRB’s mission, or policies and procedures; failure to attend IRB meetings on a regular basis without reasonable cause; or inability to perform the functions of an IRB member. The IRB shall initiate removal action through passage of a motion to the effect by two-thirds majority of the full board. The Chair or Director will forward the request for removal to the Vice President for Research along with a recommendation for a replacement.

**II1F Compensation**
Participation by University faculty or staff is considered a component of their job responsibilities. Regular members who are not affiliated with UNR receive reimbursement for their time for each meeting attended. Doctoral-level graduate student members will be compensated with a stipend for each semester of service.