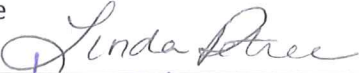




Standard Operating Procedures		
SOP #101.5 Revision 5	TITLE: Composition and Membership of the Institutional Review Board	Effective Date: 4/25/2017
Approved By: OIRB Director	Signature 	Date 4/25/2017
Approved By: IRB Chair	Signature 	Date 4/26/17

PURPOSE
To define policies and procedures for appointing Institutional Review Board (IRB) members and for maintaining the Office for Human Research Protections (OHRP) membership roster.

REVISIONS FROM PREVIOUS VERSION
Add graduate students to IRB membership; remove reference to ex-officio

POLICY
The IRB at the University of New Mexico (UNM) has a minimum of five voting members sufficiently qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The membership includes a Chair, who is directly responsible for overseeing the protection of research participants by ensuring the proper review, approval, disapproval or determination of exemption from further review of research protocol submissions to the IRB, regular members and alternates. While not listed on the OHRP roster, consultants provide guidance and input regarding IRB protocol review.

IRB membership complies with requirements outlined in federal regulations to ensure appropriate diversity of the members through consideration of multiple professions/disciplines, ethnic and cultural backgrounds, gender, and sensitivity to such issues as community attitudes and representation of the general perspectives of human subjects. In addition, the IRB includes members who can determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB regularly reviews research involving a vulnerable category of subjects, the IRB membership includes individuals who are knowledgeable about and experienced in working with those subjects.

The IRB includes at least one member with each of the following primary affiliations: nonscientific, scientific, and nonaffiliated (i.e. not currently affiliated with or retired from UNM and not part of the immediate family of a person affiliated with or retired from UNM). Nonscientific and nonaffiliated members help represent the perspective of research participants. In addition, the IRB invites individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. Alternate members are appointed to the board in general and do not serve as alternates to specific individual board members. Individuals who are responsible for business development are prohibited from serving as ex-officio members and carrying out day-to-day operations of the review process.



RESPONSIBILITIES

Execution of SOP: Office of the IRB (OIRB) Director, OIRB Staff, Institutional Official (IO), IRB, IRB Chairs.

PROCEDURE

1. The IO or designee, in collaboration with the IRB Chair and OIRB Director appoints, evaluates, and removes IRB members to ensure that composition of the IRB is in compliance with federal regulations.
2. Solicitation for new members is based on need as well as expertise and knowledge required for conducting regulatory and ethical review of protocols.
3. Individuals being considered as IRB members must submit a new member information form, current CV or resume and complete new member orientation. CVs will be submitted annually.
4. Individuals being considered as IRB members may not be responsible for UNM's business development functions (e.g. Director of Sponsored Projects, VPR, etc.).
5. Appointment letters will be sent to the member (with a copy to their department chair or dean, as applicable) and will include the term of their appointment.
6. The standard term of appointment of IRB members is 3 years. Graduate student members term of appointment is 1 year. Members may request to serve additional terms. Reappointment will be based upon the member's history of good performance, contribution, and attendance at IRB meetings.
7. IRB Chairs will be appointed by the IO or designee in consultation with the OIRB Director. IRB Chairs will typically be UNM faculty with previous experience on the IRB. Term of appointment is 1 year with the option to serve additional terms.
8. IRB Chairs will have knowledge to enforce consistent application of the ethical principles of the Belmont Report and the federal regulations and IRB policies governing human research protections. Responsiveness to the concerns of IRB members as described in the chair evaluation survey, ability to manage the efficient and effective conduct of IRB meetings, attendance and/or participation in UNM's human research protections program are factors that may be used to make appointment and removal determinations. The Chairs will have standard voting privileges as members of the IRB. Vice Chairs will serve on behalf of the Chair in his/her absence.
9. Appointment and removal of members and Chairs are at the discretion of the IO or designee, as appropriate.

REFERENCES

45 CFR 46.103(b)(3)
45 CFR 46.108(b)
21 CFR 56.108(c)
21 CFR 56.115(a)(f)
34 CFR 356.3