

Guidance and Procedures Number: 65

Title: IRB Membership

Date of Last Revision: March 6, 2009

I. IRB Membership Composition

- A. In accordance with DHHS regulations at 45 CFR 46.107 and FDA regulations at 21 CFR 56.107, each UCLA IRB shall meet the following requirements:
- (1) Consist of at least five members. Overlapping membership between Boards is permitted;
 - (2) Include at least one scientist member;
 - (3) Include at least one non-scientist member (i.e., Non-Scientific Member);
 - (4) Include at least one member who is not otherwise affiliated with UCLA and who is not part of the immediate family of a person who is affiliated with UCLA (i.e., Non-UCLA Affiliated Member);
 - (5) Be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote complete and adequate review of research activities commonly conducted by individuals at UCLA;
 - (6) Be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice;
 - (7) When reviewing research involving a vulnerable population, such as children, prisoners, pregnant women or handicapped or mentally disabled persons, the IRB shall include one or more members who are knowledgeable about and experienced in working with these subjects (i.e., Subject Representative).
- B. Each UCLA IRB will maintain appropriate community member representation according to the following standards:
- (1) Comply with all Federal and UCLA requirements for non-affiliated member representation.
 - (2) Maintain diversity of representation to reflect potential research subject candidate population.
 - (3) Ensure adequate attendance.

- (4) Ensure adequate representation of the cognitively impaired.
 - (5) Encourage non-affiliated members' active participation.
- C. The Vice Chancellor for Research and the OPRS Director shall periodically, but no less than annually, review and adjust the membership of the IRBs to ensure that the composition meets all regulatory and organizational requirements.

II. Member Nomination, Selection and Service

The nomination, selection and service of all IRB members, including Chairs and Vice Chairs, shall be according to policies established by the UCLA Human Research Policy Board.

III. Member Compensation

Stipends or other compensation provided to IRB members shall be according to policies established by the UCLA Human Research Policy Board.

IV. Alternate Members

- A. Alternates are designated for specific members. If both the alternate and primary member attend a meeting, only one of these two may vote. When an alternate member substitutes for a primary member, the alternate member will receive and review the same material that the primary member received or would have received.
1. Alternate members should have equivalent expertise, including the same scientific or nonscientific status, as the primary member for whom they are substituting.
 2. Representatives of the same department may share a membership in order to represent a speciality when it would not otherwise be possible due to conflicting commitments or schedules.
 3. Senior staff of OPRS, as designated on the IRB registration maintained with OHRP, may be designated as alternates for non-scientific members.

V. Consultants

Either before or during review of a protocol, the IRB or OPRS may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that routinely available on the IRB. Consultants may be asked to provide their expertise regarding a specific issue, or provide general comments regarding a project. Consultants may not vote with the IRB. See [HRPP Guidance & Procedure #16: IRB Process– Consultant Review](#) for additional information.

VI. Conflict of Interest

Member conflicts of interest are defined and handled according to [HRPP Policy #67: IRB Member Conflict of Interest](#).

VII. Evaluation of IRB members

- A. IRB members are evaluated on an ongoing basis by the OPRS Director and Chairs of the IRB. Such evaluation shall occur no less than annually.
 - 1. Members complete a self-evaluation form, which is reviewed by the IRB Chair and Director or Assistant Director.
 - 2. Performance is assessed according to the IRB member's meeting attendance records, level of participation during and outside of meetings, thoroughness of reviews, maintenance of confidentiality, and understanding of the regulations. When necessary, the Director and/or Chair will meet privately with a member to discuss concerns about their performance.
- B. Chairs and Vice Chairs shall also be evaluated on an ongoing basis by the OPRS Director. Such evaluation shall occur no less than annually.
 - 1. Chairs and Vice Chairs also complete a self-evaluation form, which is reviewed by the Director, Assistant Director, and IRB Administrator.
 - 2. Performance is assessed according to the same standards as members. In addition, Chairs and Vice Chairs shall also be assessed according to leadership ability, meeting management, engagement in the expedited review process, and effectiveness as representatives of the IRBs.

VIII. Confidentiality Agreement

IRB members are required to sign a Confidentiality Agreement, and must agree not to discuss, disclose, or reproduce any confidential IRB information, except as necessary to carry out IRB membership responsibilities or as required by law.

IX. Liability coverage for IRB members

Members of the IRBs, including lay members, are covered under the California Tort Claims Act of 1963. This act requires the Regents of the University of California to provide defense and indemnification with respect to claims resulting from the acts or omissions of University employees (or former employees) when acting in the course and scope of University employment, except where the employee acted or failed to act because of fraud, corruption or actual malice. Coverage is under the University of California Professional Medical and Hospital Liability Self-Insurance Program.

X. Absence of the IRB Chair

Whenever the Chair is not available to perform his or her duties, the Chair may designate the IRB Vice Chair or another IRB member to assume his or her responsibilities during his or her absence.

XI. Documentation of Membership

- A. OPRS is responsible for filing and maintaining IRB Registration with OHRP.
 - 1. The IRB Registration shall serve as the official record of the primary members for whom alternate members may substitute.
- B. The OPRS Director or an Assistant Director shall notify OHRP within thirty (30) business days of changes to IRB membership. Copies of the modified IRB Registration will be retained by OPRS.
- C. The Administrator of each IRB Committee is responsible for maintaining a record for each current member, including but not limited to the member's *curriculum vitae*, any letters of appointment, renewal or recognition, and the member's signed confidentiality agreement.
 - 1. Records relating to past members shall be stored according to Federal regulations regarding storage of IRB records.
- D. The Administrator of each IRB Committee is responsible for maintaining a roster of members.
- E. OPRS shall make available to the research community rosters of all five IRBs. These rosters shall be available upon request.

Regulations:

45 CFR 46.107
45 CFR 46.109
21 CFR 56.107
21 CFR 56.109

References:

UCLA IRB Member Confidentiality Agreement

UCLA Human Research Policy Board Policy Statements - April 2003