



Title: IRB Composition and Membership
Standard Operating Procedure: #4
Department: Human Research Protection Program/Institutional Review Board
Original Publication Date: March 22, 2010
Revision Date: September 2017

Subject: IRB Composition, Membership, and Member Expertise

Policy:

This policy states the requirements for the composition of the Institutional Review Board (IRB) at Lawrence Livermore National Laboratory (LLNL). The IRB shall be able to ascertain the acceptability of the proposed research in terms of institutional regulations, acceptable law, standards of professional conduct and practice. The IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions and of both sexes shall be considered for membership. IRB membership shall not consist entirely of men or of women. LLNL will make every effort to maintain a diverse membership of the IRB, while still within the scope of available expertise needed.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural background, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes. The IRB will have at least five members. There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no other affiliation with LLNL, either self or family member. ***For Food and Drug Administration (FDA) regulated research, there shall be at least one member who is a licensed physician.***

Procedures:

The IRB members shall be sufficiently qualified through experience and expertise, for reviewing human subjects research proposals.

In accordance with federal policy on the Protection of Humans Subjects (DHHS Regulations 45 CFR Part 46) IRB Membership must include:

1. Scientific Members
2. Nonscientific Members
3. Nonaffiliated (Public) Members
4. Representatives of Special Groups of Subjects, if applicable
5. Chair

Scientific Members: Ph.D. level scientists and physicians (M.D.s) and others who have conducted research involving human subjects. Scientific members are expected to contribute to the evaluation of a study on its scientific merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to adequately assess the protocol.

Nonscientific Members: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not primarily in the medical or scientific fields.

Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess a protocol adequately.

Nonaffiliated (Public) Members: Nonaffiliated members are expected to provide input regarding their knowledge about the community and be willing to discuss issues and research from that perspective. The nonaffiliated members should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

Consultants: The IRB may obtain guidance or additional information in order to conduct an adequate study evaluation. This may include the request of a consultant with expertise in the area of research under review by the IRB. The IRB will request a written review from the expert consultant, who will present their findings relative to the scientific merits of the study and risks and benefits to subjects. The IRB may request that the consultant attend the meeting for participation in the discussion. However, the consultant is not a voting member of the board and may not vote nor may his/her attendance count toward quorum requirements. The IRB Chair and the IRB Manager identify potential consultants. IRB members may also obtain consultations by directly contacting colleagues for information. All consultants are subject to the conflict of interest policy for LLNL and must verify that they have no conflict. (For further information, contact the LLNL Ethics Office.)

Representatives of Special Groups of Subjects: When certain types of research are reviewed, members who are knowledgeable about the concerns of certain groups may be required. For example, a prisoner advocate for research where the study population is prisoners.

In order to conduct IRB meetings, a majority (half of the members plus one) of IRB must be present at convened meetings and at least one member whose primary concerns are in nonscientific areas must be present during the course of the meeting. If quorum is not met during a meeting, ***the IRB may not take further actions or votes until quorum is met or restored.*** An IRB can lose quorum when members with conflicts of interest leave the meeting for deliberation and voting. In addition, if the IRB reviews research in which prisoners are study subjects, the prisoner representative must be present as a voting member. Attendance of the IRB members at meetings is officially recorded, noted in the minutes and reviewed monthly.

An IRB roster will be maintained for each IRB committee. Changes in IRB membership shall be reported to the Human Research Protections Office, in accordance with LLNL's Federalwide Assurance. The IRB roster will contain:

- Names of IRB members
- Earned degrees
- Scientific status
- Representative capacity
- Indications of experience
- Relationship to LLNL/Affiliation status (e.g., unaffiliated or consultant)
- Office held within the IRB (Chair, Vice Chair, Ex Officio, Member)
- Membership status
- Alternates to the IRB (*if applicable*)
- Telephone number(s), e-mail address, and fax

§46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall 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 respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall 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. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each 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.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite 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. These individuals may not vote with the IRB.

References:

45 CFR 46.103(b)

45 CFR 46.108(b)

45 CFR 46.107