

Title: IRB Composition and Membership

Standard Operating Procedure: # 4

Department: Human Research Protection Program/Institutional Review Board

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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. The IRB shall be able to ascertain the acceptability of the proposed research in terms of institutional regulations, applicable law, and 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. Lawrence Livermore National Laboratory 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. 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 Protections of Human Subjects (DHHS Regulations 45 CFR Part 46) IRB Members must include:

1. Scientific Members
2. Nonscientific Members
3. Nonaffiliated (Public) Members
4. Representatives of Special Groups of Subjects
5. Chairperson

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 and statistical 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.

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.

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 local 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 committee and may not vote nor may his/her attendance count toward quorum requirements. The IRB Chair and the IRB Administrator 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 they have no conflict. (For further information, contact the LLNL Staff Relations Conflict of Interest Coordinator.)

In order to conduct IRB meetings, a majority (half of the members) of IRB members 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, when 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 meeting is officially recorded and 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 Office of Human Research Protections, 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*)
Identification of home department
Term end dates (*if applicable*)
Telephone number(s), e-mail address, fax, and pager

References:

45 CFR 46.103(b)

45 CFR 46.108(b)

45 CFR 46.107