



Standard Operating Procedure: #2
IRB Composition, Member Expertise, and Responsibilities
Revision Date: October 2020

Overview:

This policy describes the requirements for the composition of the Institutional Review Board (IRB) at Lawrence Livermore National Laboratory (LLNL). The composition of the IRB ensures that it can ascertain the acceptability of the proposed research in terms of institutional regulations, acceptable law, standards of professional conduct and scientific practice.

The membership of the IRB shall consist of at least five (5), regular voting members and shall be diverse, so selection of new members includes 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.

The LLNL IRB may, at 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. This individual may not vote but the IRB will rely on their expertise when making determinations *i.e.*, for Food and Drug Administration (FDA) regulated research, IRB review may include a licensed physician as a guest at a convened meeting.

Policy:

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 Human Subjects (DHHS Regulations 45 CFR Part 46) IRB Membership must include:

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

Chair: The IRB Chair is a voting member of the IRB with experience in conducting and reviewing human subjects research. The Chair ensures that the IRB adheres to all regulatory requirements and chairs all convened meetings.

Scientific Members: 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. Examples of scientific members include physicians, nurses, PhD level physical or biological scientists, medical laboratory technicians, or others who have conducted research involving human subjects.

Nonscientific Members: Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess a protocol adequately. Requiring a diversity of disciplines ensures

the inclusion of 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. Examples of nonscientific members include attorneys, clergy members, ethicists, etc.).

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 (if applicable): The IRB may obtain guidance or additional information to conduct an adequate study evaluation. This may include the request of a consultant with expertise in 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 a convened 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 Program 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 (if applicable): 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.

IRB Meetings:

A quorum must be maintained to act or call for a vote at a convened meeting. A majority (half plus one) of the IRB members, at least one nonscientific member, and at least one non-affiliated member must be present throughout the meeting to maintain a quorum. Should members with conflicts of interest leave the meeting for deliberation and voting, it could negate quorum.

A convened meeting that has not met quorum can continue with reviewing studies to provide the investigator feedback to improve the submission, but cannot conduct any official business, *i.e.*, vote for approval.

If a representative of a special group of subjects is deemed necessary, the representative must be present as a voting member, *i.e.* a prisoner representative for a study involving prisoners.

IRB Roster:

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

- Names
- Earned degrees
- Representative capacity (scientific, nonscientific, nonaffiliated, etc.)
- Indications of experience (certificates or licenses to describe anticipated contribution to IRB deliberations)
- Relationship to LLNL/Affiliation status (e.g., unaffiliated or consultant)
- Office held within the IRB (Chair, Program Manager, Ex Officio, Member)
- Telephone number(s), e-mail address, and home/office location

IRB Institutional Official (IO) Responsibilities

The IRB IO is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance and has the following responsibilities:

- Creates a culture that promotes and upholds the highest ethical and scientific principles in the review and conduct of human research.
- Ensures the independence, authority, and standing of the IRB within the institution to demonstrate a commitment to human subject protections.
- Provides sufficient resources, space, and staff to maintain the Human Subjects Research Program and assesses resources on an annual basis.
- Supports IRB authority and decisions.

IRB Chair Responsibilities

The IRB Chair reports directly to the Institutional Official (IO) and has the following responsibilities:

- Determine the type of review appropriate for new protocols (exempt, expedited, full board).
- Serve as primary reviewer of protocols when appropriate. Delegate this responsibility to another IRB member or IRB Program Manager (PM).
- Conduct the business of full board meetings following basic parliamentary rules.
- Conduct New Board Member Training.
- Review unanticipated problems involving risks to subjects or others/serious adverse experience reports.
- Recommend to the IO new and/or replacement IRB members.
- Review reports of non-compliance with the IRB PM.
- Assess and recommend appropriate IRB training for the IRB, investigators, and support staff.
- Determine and establish, as necessary, educational and training meetings or workshops directed at investigators and their research staff that include LLNL policies and procedures as well as federal regulatory requirements.
- Report potential conflict of interests to the IRB PM prior to the official review of submitted IRB applications.
- Maintain the confidentiality of IRB meeting discussions.
- May present information at LLNL departmental meetings or give scheduled lectures to emphasize selected aspects of human subject research, and to keep various constituencies abreast of activities of the IRB.

IRB Program Manager Responsibilities

The IRB Program Manager (PM) serves as the subject matter expert and reports directly to the IRB Chair and has the following responsibilities:

- Communicate program requirements, guidance, and updates to Investigators and Board Members.
- Ensure, on behalf of the IRB, that revisions to protocols/consent documents are completed as required and as a condition of approval.
- Review all submitted materials for completeness and distribute materials to Board Members.
- Ensure that submitted protocols receive an efficient review.
- Comply with LLNL IRB policies and procedures.
- Serve as primary point of contact for the IRB, Investigators, and DOE site or external IRBs.
- Coordinate new board member training sessions.
- Maintain and update Federalwide Assurance with the Department of Health and Human Services, Office for Human Research Protections, as required.
- Ensure SOPs, policies, and website content is current and approved by the IRB Chair.

- Develop policies and procedures, as needed, for external/collaborating organizations, *e.g.*, Memoranda of Understanding, reliance agreements, etc.
- Provide unanticipated problems involving risks to subjects or others/serious adverse experience reports for IRB Chair review.
- Participate in continuing education training to maintain subject matter expertise and to fulfill requirements of the Certified IRB Professional (CIP) designation.
- Serve as primary member, representing LLNL, on the DOE Human Subjects Working Group.
- May present information at LLNL departmental meetings or give scheduled lectures to emphasize selected aspects of human subject research, and to keep various constituencies abreast of activities of the IRB.

IRB Administrative Staff Responsibilities

The IRB administrative staff has the following responsibilities:

- Verify that IRB and Investigators have completed all required training.
- Assist with the determination of who will serve as primary and secondary reviewers.
- Coordinate IRB convened meetings and logistics.
- Generate draft minutes of meetings for review and approval by PM and Chair.
- Generate and provide, in cooperation with the Chair/PM, correspondence to IRB, Investigators, and additional contacts as needed.
- Maintain the DOE IRB database with all pertinent project information.
- Maintain all records, including training records for members and investigators.

IRB Member Responsibilities

The IRB Member reports directly to the IRB Chair and has the following responsibilities:

- Attend convened IRB meetings.
 - Notify IRB Program Manager of unavailability in advance of the convened meeting.
 - May attend in person or via telephone.
- Active participation at convened IRB meetings.
 - Review materials distributed prior to the meeting.
 - Discuss materials, and/or business presented at the meetings.
- Serve as voting member to ensure quorum at convened meeting.
- Serve as a reviewer for expedited protocols, as needed.
- Review IRB articles and other information distributed by the LLNL IRB staff to remain informed about requirements related to participation of human subjects in research.
- Comply with LLNL IRB policies and procedures and training requirements.
- Report potential conflict of interests to the IRB PM prior to review of submitted IRB proposals.
- May present information at LLNL departmental meetings or give scheduled lectures to emphasize selected aspects of human subject research, and to keep various constituencies abreast of activities of the IRB.
- Maintain the confidentiality of all IRB related discussions.

References:

45 CFR 46.103(b)
 45 CFR 46.107
 45 CFR 46.108



Document Review History

Revision Number	Date	Author	Summary of Changes
01	September 2017	Ann-Marie Dake	Complete Revision
02	November 2018	Dawn Whalen	Document control process added
03	November 2019	IRB Office	Complete Revision
04	October 2020	Ann-Marie Dake	Revisions and updates