IRB Institutional Review Board

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Membership and Responsibilities of the IRB

According to 45 CFR 46.113, the IRB has the authority to approve, require modification of, and disapprove proposed human subjects research. The IRB also has the authority to require progress reports from investigators, to oversee the conduct of a study, and to suspend or revoke its approval of ongoing research. Failure to comply with IRB requirements is considered serious misconduct and may be subject to sanctions including possible termination of approved research. The IRB is supported by the IRB Office. At LLNL, the IRB Chair and the IRB Office report directly to the Authorized Institutional Official (IO).

To maintain a review process that is responsive to the concerns of all involved, federal regulations require that the IRB membership reflect experience, expertise, and diversity in academic, research, and professional background; racial and cultural heritage; and a sensitivity to community attitudes. The IRB is responsible for ensuring that all approved research complies with the letter and spirit of human subject protection regulations as well as the three principles previously defined in the *Belmont Report:* respect for persons, beneficence, and justice.

IRB Members

Consistent with federal regulations, the LLNL IRB comprises at least five members from diverse backgrounds who have the professional competence necessary to completely and adequately review human subjects research activities commonly conducted by LLNL. Consideration is also given to how the member's background will contribute to the diversity of the Board. To promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, prospective Board members must also be sensitive to such issues as community attitudes.

The LLNL IRB includes:

- Both male and female members.
- At least one member whose primary expertise is in a nonscientific area.
- At least one member who is not otherwise affiliated with the Laboratory, and who is not a part of the immediate family of a person affiliated with the Laboratory.

The names and qualifications of current IRB members are included on the About the IRB page.

Members are appointed by the Authorized IO, at the recommendation of the IRB Chair. Appointments are for three-year terms. Terms are renewable at the discretion of the IRB Chair and with the concurrence of the member. New members attend their first meeting as observers only. Members do not receive financial compensation.

Attendance Expectations

IRB members are responsible for attending all scheduled IRB meetings, reviewing all assigned materials, and participating in IRB discussions. Members are asked to notify the IRB Office of their impending absence at least two weeks prior to the scheduled IRB meeting, or as soon as practicable.

Conflicts of Interest

In the event that an IRB member has a conflict of interest with any protocol submitted for review, that member must disclose this conflict to the IRB Chair prior to the Board's review of the protocol. They may respond to questions from Board members. However, they must remove themselves from the room prior to the Board's deliberation and vote on the protocol. The official minutes will reflect that the member removed him/herself from the IRB meeting during the final discussion and vote on the protocol.

Board Member Education Programs

All new IRB members receive an orientation from the IRB Office before starting their active service. This orientation includes an overview of the federal regulations (45 CFR 46, 21 CFR 50 and 21 CFR 56) established to protect human research subjects, the *Belmont Report*, and other documents/materials pertaining to the protection of human research subjects at LLNL. Copies of these materials will be made available to new Board members at their orientation. Selection and teaming of new members with mentors will be by mutual agreement.

The IRB Office staff will provide continuing education and support to all IRB members. Members receive a copy of the *IRB Advisor* monthly. Human subjects research-related news articles will be provided to IRB members as deemed appropriate by the IRB Chair or IRB Program Manager. Other pertinent reference materials relating to human subjects research issues are available for review in the IRB Office. The IRB Office will also, on occasion, sponsor educational lectures. All IRB members will be strongly encouraged to participate in scheduled educational events.

Participation in the Expedited Review Process

All Board members are asked to participate in the expedited review process. Based on experience and background, the IRB Chair and Program Manager will appoint one or two Board members to review protocols qualifying for expedited review. During the review process, each reviewer is asked to contact the IRB Program Manager, as needed, and write a final report with his/her decision to approve the protocol or to refer it to full Board for review. Reviewers are asked to complete an initial review of the protocol within 5 working days and communicate those results to the IRB Office.

Removal from the Board

Recommendations for removal, along with a written justification, must be presented by the IRB Chair to the Authorized IO for consideration and final decision (except in cases of absenteeism).

IRB Chairperson

The Chair is appointed by the Laboratory's Authorized IO and serves at the IO's discretion. Only senior level staff may recommend that a Chair be removed from office. This recommendation, along with a written justification, must be presented to the Authorized IO for consideration and final decision.

The Chair is a voting member on all IRB issues unless s/he has a conflict of interest with a protocol under IRB review. The duties of the IRB Chair include moderating meetings, performing expedited reviews, consulting with investigators as needed, coordinating other efforts with the IRB administrative staff as needed, and recommending new members to the Authorized IO for consideration and final appointment. Typically, the Chair does not sit on any of the IRB subcommittees.

Institutional Official

The Institutional Official (IO) is the individual legally authorized to act for the institution, and on behalf of the institution, obligates the institution to the Terms of the Assurance at the Office of Human Research Protections.

The IO is responsible for ensuring the Human Research Protection Program (HRPP) functions effectively and that the institution provides resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA).

The IO should be someone of sufficient rank who has the authority to ensure that all obligations of the HRPP are carried out effectively and efficiently. At LLNL, the IO is the Deputy Director. The IO should be at a level of responsibility sufficient to allow authorization of necessary administrative or legal action, should that be required. Thus, department chairs, division directors or other officials who only have authority over one portion of the institution would generally not be an appropriate IO. Similarly, the Office for Human Research Protections (OHRP) recommends that the IO not be the chair or member of any IRB designated under the FWA.

The general administrative obligations of the IO are as follows:

- Designating one or more IRBs that will review research covered by the institution's FWA.
- Appointing the IRB Chair and IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations.
- Managing and administering funds. Ensuring that adequate personnel, space, and other sufficient resources are allocated to the HRPP to support the IRB's review and record keeping duties.
- Providing training and educational opportunities for the IRB and investigators.
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest level of the organization.
- Ensuring effective institution-wide communication and guidance on human subjects research.
- Ensuing that investigators fulfill their responsibilities.
- Encouraging all staff engaged in the conduct or oversight of human subjects research to participate in education activities.

- Serving as a knowledgeable point of contact for correspondence addressing human subjects research with OHRP, FDA and other agencies as applicable, including reports to federal agencies, or delegating this responsibility to another appropriate individual.
- Performing periodic evaluation of the performance of the IRB char, co-chairs, and staff.
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organization, including those that establish reliance on IRBs of record of collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements, Reliance Agreements, Inter-Agency Agreements).
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.

Note:

- **The IO cannot approve research that has been disapproved (or not approved) by the IRB.**
- **The IO may delegate the performance of certain oversight and operational duties to one or more individuals. Any delegation of duty must be in writing.**
- **Depending on the organizational structure at a given institution, other administrative arrangements may be appropriate.**