IRB Institutional Review Board

#1
Research: A Shared Responsibility

Directorates across Lawrence Livermore National Laboratory (LLNL) are working on research projects to further our knowledge of human biology, to develop technologies for the detection and treatment of disease, and to contribute to the security of the nation. The use of human subjects in these research activities falls under the jurisdiction of federal regulations. LLNL investigators are granted the privilege of involving human subjects in their research under the terms of a formal assurance with the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS). All LLNL investigators who conduct, support or review research involving human subjects must comply with the regulations identified in this assurance, as well as applicable state and institutional policies and standards of professional conduct and practice. Failure to comply with the terms of the assurance can result in loss of funding for human subjects research. Noncompliance by one investigator can affect the ability of all others at LLNL to do human subjects research.

Federalwide Assurance (FWA) #00004274, maintained with the OHRP at DHHS, requires that all human subjects research conducted by LLNL investigators, or otherwise under the auspices of LLNL, be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) [**Note:** 45 CFR 46 consists of Sub-parts A, B, C, D, and E. Sub-part A is also known as the "Common Rule." The text of this rule was agreed upon by seventeen government agencies and published in the Federal Register on June 18, 1991. The agencies all agreed to promulgate the same regulations based on this Common Rule so that human subjects research would be regulated consistently across the government. The Federal Register made it clear that each agency would implement the Common Rule through its particular regulations; the Department of Energy (DOE) does so through 10 CFR 745. LLNL's FWA with DHHS commits the Laboratory to implementing all sub-parts of 45 CFR 46, not just the Common Rule. Therefore, when referencing federal regulations, this manual will use the DHHS regulations (45 CFR 46) instead of DOE regulations (10 CFR 745) when referring to elements of the Common Rule.]. In addition, the actions of LLNL must also conform to all other applicable federal, state, and local laws and regulations, including U.S. Food and Drug Administration (FDA), DOE, and LLNL policies and procedures.

It is also LLNL's policy that investigators respect and protect the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of the Laboratory.

In the review and conduct of research involving human subjects, LLNL is guided by the ethical principles set forth in the *Belmont Report* (i.e., respect for persons, beneficence, and justice).

As delegated by the Laboratory's Director, LLNL's Institutional Review Board (IRB) has the primary responsibility for the oversight of the protection of human subjects who have been recruited to participate or are actively participating in research projects conducted by or with the assistance of LLNL investigators.

This document provides information about the ethical conduct and review of human subjects research at LLNL. It explains the various federal and state regulations and institutional requirements, and provides guidance for investigators and IRB members regarding the development, review, and conduct of human subjects research.

The information presented here is the most current available. However, the field of human subject protection continues to evolve. Investigators and IRB members are encouraged to check the IRB website for revisions or updates.

The IRB Office is also available to answer any questions investigators may have regarding the participation of human subjects in research.

The Laboratory, research staff, IRB Office, and IRB share collective responsibility for the ethical conduct of human subjects research. To be effective, this collaborative responsibility requires a culture of trust, openness, and honesty. LLNL must uphold the highest ethical principles in the conduct of research. By upholding the highest standards in a safe research environment, LLNL can build public support for the pursuit of greater knowledge.

The dignity and welfare of individuals who participate in research is a central concern in the protection of human subjects. Our primary goal must be to assure the development of a fair and explicit process in which subjects voluntarily decide to participate in a study based on an intelligent and knowledgeable assessment of the risks and benefits of the research.

Review of human subjects research performed by investigators (i.e., employees, participating guests, students, or contractors) of LLNL is required. This review is conducted by the Laboratory's IRB. Composition of the IRB is mandated by the federal regulations, which require scientific and nonscientific individuals from various directorates at LLNL, as well as community representatives who are not affiliated with the Laboratory.

The IRB is charged with a twofold mission to (1) determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth by the DHHS and DOE regarding the health, welfare, safety, rights, and privileges of human subjects and (2) assist investigators in conducting ethical research that complies with the DHHS regulations in a way that permits accomplishment of the research activity.

The mission is accomplished through IRB review of protocols, discussion between investigators and the IRB during the review process, and IRB/IRB Office outreach to the research community. The process serves to ensure the safe and ethical conduct of human research and the protection of the rights and welfare of human subjects.