Title: IRB Institutional Authority
Standard Operating Procedure: #5
Department: Human Research Protection Program/Institutional Review Board
Original Publication Date: March 22, 2010
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Subject: Institutional Authority of the IRB

Policy:

In accordance with the federal policy on the protection of Human Subjects (DHHS Regulation 45 CFR 46, FDA Regulation 21 CFR Parts 50 and 56), Lawrence Livermore National Laboratory (LLNL) is responsible for the protection of the rights and welfare of humans subjects in research conducted by, or under the supervision of LLNL investigators and staff. To conduct this responsibility effectively, the Laboratory has delegated responsibility for the LLNL human subjects protection program to the Deputy Director of the Laboratory. Under the authority of the Deputy Director, an Institutional Review Board (IRB) had been established and empowered to oversee human subjects research.

45 CFR 46 Section 103(a) requires that each institution engaged in federally sponsored human subjects research file an "Assurance" of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects participating in research. LLNL, as part of its Federalwide Assurance (FWA#00004274), has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore, the LLNL IRB has oversight over all human subjects research conducted at LLNL, or by its investigators and staff.

The IRB shall have the authority to:

- Approve, require modifications, or disapprove all human subjects research activities conducted under the auspices of LLNL.
- Suspend or terminate approval of any human subjects research studies.
- Observe or have an observer present during the consent process of human subjects research studies.
- Require progress reports from the investigators and oversee the conduct of any human subjects research studies.
- Place restrictions on any human subjects research study.

IRB members and IRB staff shall not be unduly influenced. Any attempt to unduly influence an IRB member or IRB staff shall constitute research misconduct. Any person attempting to unduly influence committee members or staff will be reported to the Authorizing Institutional Official and investigated under the LLNL Research Misconduct Policy.

References:
45 CFR 46
21 CFR 50, 56, 312, 812
Research Misconduct Policy