

**Title: Institutional Federalwide Assurance of Compliance
Standard Operating Procedure: #2
Department: Human Research Protection Program/Institutional Review
Board
Original Publication Date: March 22, 1010
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Subject: Institutional Federalwide Assurance of Compliance That the Rights and
Welfare of Human Subjects Are Protected

Policy:

All human subjects research undertaken by Lawrence Livermore National Laboratory (LLNL) and all activities of the Institutional Review Board (IRB) designated under its Federalwide Assurance of Compliance (FWA00004274) will be guided by the ethical principles of the *Belmont Report* and by the other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects.

The terms of the LLNL Federalwide Assurance of Compliance will apply whenever LLNL becomes engaged in human subjects research, which is not otherwise exempt from the Federal Policy for the Protection of Humans Subjects. See Standard Operating Procedure #7, *Activities Subject to IRB Review*. The terms of LLNL's Federalwide Assurance of Compliance will apply to research regardless of the funding source or study location.

All research activities designated under LLNL's Assurance will comply with the Common Rule (45 CFR 46). This includes all Subparts (A, B, C, D, and E) of the Common Rule. All federally supported research will also comply with any additional regulations and policies of the supporting federal department or agency. LLNL's Assurance is based on the following principles:

- Safeguarding the rights and welfare of human participants in research is an institutional policy delegated by the Laboratory's Deputy Director, who is the Authorizing Institutional Official (AIO) for the IRB. It is the AIO's responsibility to exercise appropriate administrative oversight to assure that LLNL's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance.
- LLNL's research activities are subject to the Assurance and its underlying policies. This includes any research for which an Assurance or other formal agreement (e.g., MOU) identifies LLNL's IRB as the IRB of Record.

- LLNL further agrees to apply additional federal regulations such as U.S. Food and Drug Administration's Human Subjects Regulations (21 CFR 50, 56, 312, and 812); and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants under IRB purview.

Procedures:

1. A copy of LLNL's Federalwide Assurance of Compliance will be maintained in the Human Research Protection Program Office and made available to the LLNL community at any time.
2. The AIO will ensure, with the assistance of the staff of the Human Research Protection Program Office, that this Assurance is updated at least every 36 months, even if no changes have occurred, in order to maintain an active Assurance for LLNL. Amendments to the Assurance are to be reported promptly to DOE's Office of Human Resource Protections (OHRP). This includes changes to the IRB committee membership.
3. The Office of the AIO will provide the IRB with resources and professional support staff sufficient to effectively carry out its responsibilities under the Assurance.
4. Annually, the IRB budget will be reviews by the AIO and modified as necessary to accommodate the volume and type of research reviewed, and the space, facilities, and staff needed.

References:

45 CFR 46
21 CFR 50, 56, 312, 812
HIPAA Regulations