Title: Institutional Federalwide Assurance of Compliance
Standard Operating Procedure: #2
Department: Human Research Protection Program/Institutional Review Board
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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 Authorized Institutional Official (IO) for the IRB. It is the IO'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., Memorandum of Understanding [MOU], Intent to Rely, IRB Authorization Agreement) 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.

2. This Assurance is updated at least every 36 months, even if no changes have occurred, in order to maintain an active Assurance for LLNL.
3. The Office of the IO will provide the IRB with resources and professional support staff sufficient to effectively carry out its responsibilities under the Assurance.

§46.501 What IRBs must be registered?
Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§46.502 What information must be provided when registering an IRB?
The following information must be provided to HHS when registering an IRB:
(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:
(i) All active protocols; and
(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an ``active protocol'' is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§46.503 When must an IRB be registered?
An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under §46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§46.504 How must an IRB be registered?
Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with §46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

References:
45 CFR 46
21 CFR 50, 56, 312, 812