



**Standard Operating Procedure: #1**  
**Overview of the Human Subjects Research Program (HSRP) at Lawrence Livermore**  
**National Laboratory**  
**Revision Date: November 2020**

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**Lawrence Livermore National Laboratory Institutional Review Board**

It is the goal of Lawrence Livermore National Laboratory (LLNL) to ensure that all research involving humans as participants, conducted under the auspices of LLNL, complies with all federal and state laws, as well as Lawrence Livermore National Security, LLC policies regarding the protection of human subjects in research. As described in its Federal wide Assurance of Compliance (FWA00004274) with the Office of Human Research Protection (OHRP), LLNL has elected to apply the Common Rule (45 CFR 46) and the principles of the *Belmont Report* to all human subjects research (HSR) in which it is engaged, regardless of sponsorship.

The protection of human subjects in all the research performed under U.S. Department of Energy (DOE) authorities is of prime importance to the Department. All research conducted at DOE institutions, supported with DOE funds, or performed by DOE contractor employees and/or their subcontractors, including research that is classified and proprietary, whether done domestically or in an international environment, must comply with all federal regulations and DOE requirements that address the protection of human subjects.

The HSRP (Human Subjects Research Program) at LLNL encompasses all research involving human subjects performed at or in conjunction with LLNL. The Deputy Director of LLNL is the HSRP authorized Institutional Official (IO). The LLNL HSRP consists of the LLNL IRB (Institutional Review Board) and the LLNL IRB program office. The LLNL IRB office provides program and administrative support for the LLNL HSRP and reports directly to the Institutional Official (IO). As required by federal and state laws, all HSR conducted under the auspices of LLNL is reviewed and approved by the LLNL IRB. The IO or designee cannot authorize HSR not approved by the IRB. However, the IO or designee has the final approval for work to be carried out at LLNL and could choose to not allow research that has been approved by the LLNL IRB.

LLNL's IRB program is prescribed by the [DOE](#) and adheres to DOE Order 443.1CC , Protection of Human Research Subjects (and subsequent revisions). Click [HERE](#) for the Department of Energy, Office of Science, Human Subjects Protection Program.

**Institutional Federalwide Assurance of Compliance Policy**

All human subjects research conducted under the auspices of Lawrence Livermore National Laboratory (LLNL) and all activities of the Institutional Review Board (IRB) designated under its Federalwide Assurance (FWA) 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 SOP #5: *IRB Review of Human Subjects Research – Initial Review*. The terms of LLNL's Federalwide Assurance of Compliance will apply to research regardless of the funding source or study location.

## Ethical Principles of the *Belmont Report*

Ethical review of research conducted by LLNL is the primary goal of the IRB. All IRB reviews will consider the ethical principles of the *Belmont Report*. Each of the regulatory requirements used as criteria for IRB approval is based on one or more of the below ethical principles. The *Belmont Report* describes how the principles of respect for persons, beneficence, and justice are relevant to research involving human subjects.

The principle of **respect for persons** demands that subjects' decisions about becoming involved in research must be voluntary and informed. Investigators have a responsibility to recruit subjects in such a manner that potential volunteers do not feel pressured to agree, and that they have ample time to discuss the study procedures and to ask questions.

**Beneficence** is the recognition that people are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts, or, more specifically, making it an obligation, to secure their well-being.

**Justice** relates to the selection of research subjects. The selection process needs to avoid targeting specific classes of subjects (*e.g.*, welfare patients, racial and ethnic minorities, or persons confined to institutions) simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the issues being studied. Whenever research leads to the development of therapeutic devices and procedures, justice demands that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of the research or that the benefits of the research provide advantages only to those who can afford them.

The selection of subjects must be fair and equitable. In assessing whether selection of subjects is equitable, the IRB considers the purposes of the research and the research setting.

Potentially beneficial research should not be offered only to subjects who are pleasant to work with; likewise, higher risk research with no potential benefit to the subjects should not be targeted only at "undesirable" populations. Social justice requires that a distinction be drawn between classes of subjects that ought, and ought not, to participate in any kind of research. This distinction should be based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (*e.g.*, adults before children) and that some classes of potential subjects (*e.g.*, the institutionalized, mentally infirm, or prisoners) may be involved as research subjects, if at all, only under exceptional conditions.

All research activities designated under LLNL's Assurance will comply with the Common Rule (45 CFR 46) and, when applicable, U.S. Food and Drug Administration (FDA) regulations 21 CFR 11, 50, 54, 56, 312, 812. 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.

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 FDA'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 subjects under LLNL IRB purview.

**Compliance with the Assurance is supported by:**

1. A copy of LLNL's FWA of Compliance is maintained in the LLNL IRB Office and can be made available to all LLNL staff.
2. An approved FWA is effective for five (5) years; however, when information changes on the FWA, an update should be submitted to OHRP. After approval, any updates to the information in your institution's FWA must also be done electronically through the OHRP Electronic Submission System.
3. The LLNL IO provides the LLNL IRB with resources and professional support staff sufficient to effectively carry out its responsibilities under the Assurance.

**Institutional Authority of the LLNL IRB**

In accordance with the federal policy on the protection of Human Subjects (DHHS Regulation 45 CFR 46, FDA Regulation 21 CFR Parts 50, 54, 56, 312, and 812), Lawrence Livermore National Laboratory (LLNL) is responsible for the protection of the rights and welfare of human subjects in research conducted under the auspices of LLNL. These auspices include research conducted by, or under the supervision of, LLNL investigators. To conduct this responsibility effectively, the Laboratory has delegated responsibility for the LLNL human subjects research program to the Deputy Director of the Laboratory. Under the authority of the Deputy Director, an Institutional Review Board (IRB) has been established and empowered to oversee human subjects research.

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.
- Report research misconduct (ex: investigator attempts to unduly influence an IRB member or staff) to the IO

**References:**

*45 CFR 46*

*21 CFR 50, 56, 312, 812*

*Belmont Report*

*Department of Energy, Human Subjects Protection Program website*

## Document Review History

Revision Number	Date	Author	Summary of Changes
01	September 2017	Ann-Marie Dake	Complete Revision
02	November 2018	Dawn Whalen	Document control process added
03	November 2019	IRB Office	Complete Revision
04	November 2020	Ann-Marie Dake	Revised