



Title: Activities Subject to IRB Review
Standard Operating Procedure: #7
Department: Human Research Protection Program/Institutional Review Board
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Subject: Activities Subject to the Lawrence Livermore National Laboratory Human Research Protection Program and IRB Review

Definitions:

LLNL Agent: A person acting on behalf of, and under the direction of Lawrence Livermore National Laboratory (LLNL) faculty, staff or students.

Research: A systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge.

Systematic Investigation: A study or examination involving methodical procedure or plan.

Generalizable Knowledge: Conclusions, facts or principles derived from particulars (e.g., individual subjects or medical records) that are applicable to or affect a whole category (e.g., members of a class, kind, group or a field of knowledge) and enhance scientific or academic understanding.

Human Subject: A living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction or (2) identifiable private information.

Intervention: Includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or school record). In order to meet the above definition, private information must be individually identifiable (e.g., the identity of the subject is known or may be readily ascertained by the investigator or associated with the information) in order for the investigation to constitute research involving human subjects. In general, private information is considered to be individually identifiable when it can be linked to a specific individual by the investigator(s) either directly or indirectly through coding systems or when characteristics of the information obtained such as that by their nature a reasonably knowledgeable person could ascertain the identity(ies) of the individual(s).

Policy:

The policy guidance in "Engagement of Institutions in Human Subjects Research," issued in 2008 applies to research at LLNL:

In general, institutions are considered engaged in a Health and Human Services (HHS)- conducted or -supported non-exempt human subjects research project (and therefore, would need to hold or obtain Office of Human Research Protections [OHRP]-approved Federalwide Assurances [FWAs] and certify IRB review and approval to HHS) when the involvement of their employees or agents in that project includes any of the conditions stated here.

Research Involving Human Subjects and Clinical Investigations: All research involving human subjects as described in [*Standard Operating Procedure #3, What Is Research Involving Human Subjects?*](#)

In all cases, investigators should contact the IRB to discuss the research project in question to obtain a determination of the type of IRB review that may be required.

Reference:

45 CFR 46.102(d,f)

21 CFR 50.3(f)

California Health and Safety Codes 102231, 125115-125117

OHRP Guidance on "[Engagement of Institutions in Research](#)"