IRB
Institutional
Review Board

#15
Initial Review Determinations

The IRB Office is responsible for providing guidance (regulatory and institutional) on matters related to IRB reviews of human subjects research, including assuring LLNL's adherence to federal regulations governing human subjects. Resources for the IRB Office are made available through funding from the Laboratory's Deputy Director. The Office works closely with Board members to develop broad-based educational activities for Board members, investigators, and the LLNL community to raise the level of awareness regarding human subjects research issues. The Office interacts with multiple levels of personnel across LLNL directorates, at DOE and other federal agencies, at University of California campuses and the UCOP, and at other IRB sites to coordinate activities and to gather, clarify, and disseminate information relevant to human subjects research at LLNL. The IRB Office is also available to assist investigators with questions or concerns they may have regarding the development or conduct of human subjects research protocols.

The IRB Office reports to the Authorized Institutional Official.

The determination that an activity involving human subjects is exempt from federal regulations is made by the IRB Office. To make this determination, the IRB Office will ask the following questions:

- **Is the activity research?** Occasionally, an investigator is unsure whether or not an activity involving human subjects would be considered research. In those cases, investigators are encouraged to contact the IRB Office for an administrative review. The IRB Office will review supporting documentation of the activity and notify the investigator if additional IRB review is required.

  45 CFR 46 defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

- **Does the activity involve human subjects or their bodily materials?** The IRB Office will review the involvement of human subjects in the research activity to ensure that they are "living individuals about whom the investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."

  Data through intervention includes both physical procedures by which data are gathered (for example, venipuncture) 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 (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) for obtaining the information to constitute research involving human subjects."

- **Is the research activity exempt from 45 CFR 46?** Some research involving human subjects or their bodily materials does not require review and approval by the IRB (see Research Eligible for Exempt Review). If an investigator believes his/her human subjects research activity falls into any of the listed categories, s/he must submit Form LL6650, Request for Exemption.

> ***Note:*** *Investigators cannot "self-exempt" from IRB review. LLNL has assured DHHS that the evaluation and certification of exempt status is performed by the IRB Office, which reviews all such activities, whether funded or not, and certifies that the research meets the federal requirements for an "Exempt Determination."*

Submitting a Protocol for Administrative/Exempt Review

When submitting a research activity to the IRB Office for an administrative review, the investigator must provide the following documents, as applicable:

- Form LL6650, Request for Exemption .
- A brief abstract of the research activity, purpose, and objectives of the study.
- Approval from other participating institutions.
- Recruitment materials (i.e., advertisements, flyers, phone scripts, etc.).
- A sample consent form or information sheet.
- Copies of surveys, educational tests, or interview scripts.
- Investigators are strongly urged to consult with the IRB Office before submitting a Request for Exemption.

Submitting a Request for Fee-for-Service Determination

When submitting Form LL6712, Request for Fee-for-Service Determination, the IRB Office will require the LLNL investigator to provide a letter from the Chair of the reviewing IRB containing the following information:

- Title of study.
- Date of IRB approval.
- Information regarding vulnerable populations (i.e., pregnant women, fetuses, children, prisoners, or the decisionally impaired). Specifically, will the study involve vulnerable populations? If yes, the vulnerable population should be identified.
- Acknowledgment that samples will be analyzed at LLNL as a fee-for-service activity.
- The reviewing IRB's Federalwide assurance number.