IRB Institutional Review Board

#6

Research Requiring Review by the LLNL Institutional Review Board

General Requirements

Any research activity that does not qualify for an administrative review must be reviewed by the IRB to determine if the rights and welfare of human subjects involved in the research activity are adequately protected. Documents provided to the IRB by investigators must contain enough information to allow valid judgments about the science and ethics of the research. After a protocol has been approved, an investigator must submit on an annual basis, an application renewal request to the IRB. The investigator must also receive approval from the IRB before any changes to the research protocol are implemented or if any subject experiences an adverse event as a result of participating in the research activity. In most cases this involves submission of Form LL6657, Request for Amendment or Modification.

Pilot Studies

Pilot studies and feasibility studies, even if they include only one subject, require the same consideration by the IRB as a project that requests the participation of 100 or more subjects. Investigators interested in conducting feasibility or pilot work should consider contacting the IRB Office prior to submitting an application. The IRB Office can advise the investigator on how to appropriately address issues related to the risks and benefits of participation.

Research Collaborations with Off-Site Institutions or Investigators

Human subjects research that involves off-site collaborations must be reviewed by the LLNL IRB as well as the collaborating institution's IRB. This is true regardless of whether the LLNL investigator has contact with the subjects or not. Additionally, LLNL IRB review is required even if LLNL investigators only have access to coded information or samples. When research involves off-site institutions, it is important that all collaborators work closely together to develop a protocol and consent form that will be acceptable to all reviewing IRB offices.

> ***Note:*** *Do not wait for the IRB approval at collaborating institutions before submitting your proposal to the LLNL IRB. If all human subjects contact occurs at the collaborating institution, and the LLNL IRB approves the project prior to your obtaining an approval letter from the collaborating institution's IRB, the LLNL IRB may, if applicable, note that your project's approval is contingent upon the receipt of your collaborator's IRB approval documents.*