IRB Institutional Review Board

#7

Basic Application Packet

Most IRB applications for human subjects involved in biomedical research consist of four (4) core documents: (1) Form LL6652, Request for Review, (2) Form LL6655, Application to Involve Human Subjects in Research, (3) Consent Form, and (4) Bill of Rights. These forms are available on the Forms page or from the IRB Office. Other documents may be required as part of the submission depending on the type of research (e.g., collaborations, FDA-regulated studies, etc.).

All investigators should carefully review the following requirements for submission of applications to the IRB. Submission of incomplete application packets will result in the delay of the review and approval process. The review process will not be initiated if the proposal is incomplete and/or does not fulfill the IRB's requirements described in Guidelines for Developing a Basic Protocol. Investigators should also pay close attention to information provided in IRB Review Process, and the guidelines provided on Form LL6655, Application to Involve Human Subjects in Research, in order to ensure that the appropriate forms are submitted for IRB consideration.

The IRB Office is available to answer any questions investigators may have regarding the participation of human subjects in research or the review of applications by the IRB.

Request for Review (Form LL6652)

Form LL6652, Request for Review, is a two (2) page document that provides the IRB with basic information about the principal investigator and the proposal. The information provided on this form will facilitate an effective review by all members of the IRB.

Application to Involve Human Subjects in Research (Form LL6655)

Form LL6655, Application to Involve Human Subjects in Research, is an official account of the intended research methods and procedures, with special attention to how the benefit is maximized, risk minimized, and autonomy respected. This protocol application clarifies what is to be done, how, and why. Additional guidance regarding the development of a protocol can be found in Guidelines for Developing a Basic Protocol.

LLNL is legally responsible for research conducted at LLNL, sponsored by LLNL, or using LLNL's nonpublic information—as are investigators and their supervisors. Therefore, IRB protocols must reflect what is actually done in the research. Once the IRB has approved a protocol for a particular project, the investigator is bound to follow that procedure. If the investigator decides to change the protocol, s/he must receive approval from the IRB prior to initiating the change.

The protocol is a control document—an official statement that specifies how the study is being conducted. It is a document that all researchers associated with the project are expected to read and follow. The protocol becomes a vital part of an official "paper trail" showing that the research is acceptable to a legally constituted board of reviewers. Should anyone raise questions about the research, the approved protocol is powerful evidence that the project is of sufficient value to justify any risks or inconveniences involved.

Consent Form

When subject contact occurs at LLNL, the LLNL investigator must create and submit a consent form to the LLNL IRB for review and approval. Guidelines for developing a consent form and a sample template (LL6660 and LL6661) are available on the Forms page. Once approved, the consent form will denote the effective and expiration dates. All subjects participating in the research must read, sign, and be given a signed copy of the approved consent form prior to participating in the research activity. Alternatively, a waiver of informed consent or a waiver of documentation of informed consent may be approved by the IRB. Please refer to The Consent Process for additional information regarding the requirements for informed consent and the stipulations for waivers.

If the protocol involves collaboration with another institution and subject contact occurs at that institution, the LLNL IRB may accept the collaborating institution's consent form in lieu of an LLNL consent form. Acceptance by the LLNL IRB depends on whether or not the collaborating institution's consent form contains the elements of consent as described in The Consent Process.

Experimental Subject's Bill of Rights

The State of California requires that all subjects enrolled in biomedical research receive a copy of the Bill of Rights (LLNL) Form LL6651. LLNL investigators are responsible for ensuring that subjects recruited for medical research at LLNL are provided with a copy of the Bill of Rights (available on the Forms page) in addition to the IRB-approved consent form.