



Standard Operating Procedure: #5
IRB Review of Human Subjects Research – Initial Review
Revision Date: October 2020

Overview:

Federal regulations require that in conducting the initial review of proposed research, Institutional Review Boards (IRBs) obtain information in sufficient detail to make the determinations required under 45 CFR 46.111 (or 21 CFR 56.111 for U.S. Food and Drug Administration [FDA]-regulated research) regarding risks, potential benefits, informed consent, and safeguards for human subjects.

Lawrence Livermore National Laboratory (LLNL) employees and/or subcontractors who conduct research, including surveys involving human subjects, are required to notify the LLNL IRB and submit an IRB application describing their proposed research when applicable. No intervention or interaction with human subjects in research, including recruitment, and no collection of data about or samples from human subjects may begin until an investigator's application to conduct human subjects research has received LLNL IRB approval, a certification of exemption, or letter indicating that the material is not human subjects research related.

The IRB review starts with a complete application submitted by the Principal Investigator (PI). To ensure an IRB determination can be made to meet the PI's desired start date for the study, the PI should contact the IRB Program Manager for submission deadline, if one is needed.

To ensure a thorough review, the PI should provide the following with the application:

1. The proposed informed consent documents, if applicable.
2. Any questionnaires or survey instruments that will be utilized to collect data for the study.
3. If the project is a collaboration between/among other institutions, copies of the IRB approval letter(s) and consent form(s) from other institutions involved in the research.
4. For FDA research, the sponsor/company protocol and investigator brochure (if one exists), for studies involving investigational drugs. The device manual should be included for studies that involve an investigational or FDA-approved device. Results of previous animal and human studies that are summarized in the investigator's brochure must also be included.
5. The recruitment materials, including advertisements intended to be seen or heard by potential participants (e.g., posters, e-mail, Internet, or radio/television advertisements).

Once received, the IRB office will determine if the study is:

- Non-Human Subject Research (NHSR) – the study does not fit the definition of human subjects research and no further IRB action is required
- SOP #6: *IRB Review of Human Subjects Research – Exempt (Limited Review)*
- SOP #7: *IRB Review of Human Subjects Research - Expedited*
- SOP #8: *IRB Review of Human Subjects Research – Full Board*



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	October 2020	Ann-Marie Dake	Revisions and updates