



#4 Investigator Responsibilities

Although the Lawrence Livermore National Laboratory (LLNL), investigators, the IRB, and the IRB Office share collective responsibility for the ethical conduct of human subjects research, the complex responsibilities of doing so can make the investigator's role particularly difficult and challenging. However, once the investigator understands the responsibilities involved, research can be rewarding for both the investigator and the subjects who participate. This policy discusses the investigators' responsibilities and provides additional information regarding the development of a human subjects research protocol and conducting a successful research study.

Any investigator who conducts research involving human subjects must comply with federal regulations governing human subjects research, as well as applicable state and institutional policies and standards of professional conduct and practice. Failure to comply with federal regulations can result in loss of funding to conduct human subjects research by the individual, the program, or the LLNL. Noncompliance by one investigator can affect the ability of all others at LLNL to do human subjects research. An investigator must:

1. Understand the ethical standards and regulatory requirements governing the research activities.
2. Recognize that IRB review and approval **must** precede initiation of any work involving human subjects.
3. Notify the IRB Office of their intention to use human subjects in research and submit required material to the IRB Office to facilitate review of research.
4. Protect the rights and welfare of the human subjects who participate in the research through proper informed consent, etc.
5. Notify the IRB Office of any adverse or unexpected events regarding subjects.
6. Notify the IRB Office of changes to the research protocol.

Presently, all LLNL investigators who are engaged or plan to be engaged in research involving human subjects must successfully complete the web-based course, HS4466-W (Biomedical [Biomed] Basic). Additional training is available from the IRB Office staff on an as-needed basis.

This website should be consulted for new and revised institutional and federal guidelines, policies and procedures, forms, etc. relating to human subjects research.

