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Human Subjects Research Defined

In defining human subjects research activities, two separate determinations must be made. The first is whether or not the activity can be considered research. If the answer is “yes,” investigators must follow up with a second determination: does the research involve human subjects? This determination must be made following 45 CFR 46’s definitions of the terms “research” and “human subjects.”

Research— “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes.” Investigators unsure of whether an activity constitutes human research should contact the IRB Office. ([The Guidelines for Defining Public Health Research and Public Health Non-Research](#) provides additional information about research in the occupational/public health environment.)

Human subjects—“living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” Investigators should note that although cadavers are not considered “human subjects,” information collected from them can result in an investigator obtaining information about the cadaver’s living relatives (e.g., genetic studies). Activities in which a researcher collects private, identifiable information about third parties would meet the definition of “human subjects.”

All research involving human subjects must be screened by LLNL’s IRB Office to determine whether further review and approval by the IRB is required. This review must take place before the research activity is initiated. The requirement applies to all research involving human subjects and all activities that even in part involve such research, if one or more of the following apply:

- The activity is sponsored, in part or entirely, by LLNL.
- Some or all of the activity is conducted by, or under the direction of, any LLNL employee or contractor worker in connection with his or her Laboratory duties.
- Some or all of the activity is conducted by, or under the direction of, any LLNL employee or contractor worker using any LLNL property or facility.
- The activity involves the use of LLNL’s nonpublic information to identify or contact human research subjects or prospective subjects.



The term “human subjects research” potentially covers a broad range of activities. The following list provides a few examples of research activities that require IRB review and approval:

- The use of human-derived data.
- The use of human cell cultures.
- Projects or pilot studies in which the investigator is the only subject.
- Research projects in which information is sought or obtained either directly from the subject (e.g., through an interview, questionnaire or survey) or indirectly (e.g., through observation of human subjects or access to identifiable private records).
- Collaborative studies in which human material or information is collected at another institution and sent to investigators at the Laboratory.
- Requests for information from third parties interested in conducting human subjects research or concerning existing human subjects research.
- Donation of tissues, organs, fluid, or other bodily material for research purposes.
- Research projects that require human subjects to participate in physical activities.
- Evaluation of medical devices that are being developed to evaluate health or detect disease.
- Research involving experimental or licensed pharmaceuticals.

Note: *When an investigator is unsure whether or not an activity involves human subjects or should be considered research, s/he should contact the IRB Office for an administrative review. The IRB Office will review supporting documentation of the activity and promptly notify the investigator of the results of the review.*

