



## #2

**The Ethical Foundations of 45 CFR 46—The Belmont Report**

The passage of the National Research Act in 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1976, the Commission published the [\*Belmont Report\*](#), which articulates the basic ethical principles that guide the conduct of research with human subjects and form the foundation for federal regulations governing the protection of human research subjects. In the report, three principles were defined as basic to the protection of human subjects: respect, beneficence, and justice. The Lawrence Livermore National Laboratory (LLNL) IRB accepts and promulgates these ethical principles.

**Respect**— In consideration of respect for persons, investigators are required to seek voluntary, written informed consent from potential subjects. Voluntary informed consent means that subjects are (1) given explicit assurances of the voluntary nature of their participation in terms that are easy to understand and (2) not under duress at the time they are asked to participate in the research. The consent form also includes adequate information about the study to assist subjects in intelligently deciding whether to participate in research. In addition, respect means honoring the privacy of individuals and maintaining the confidentiality of their data. Respect for minors and decision-impaired persons requires extra precautions to protect those individuals who are immature or incapacitated, perhaps even to the extent of excluding them from participation in certain research. The extent of protection depends on the risks and benefits of the research to the participants.

**Beneficence**— This principle requires that investigators maximize the potential benefits to the subjects and minimize the potential for harm. The probability of benefits to the subjects, or in the form of generalized knowledge gained from the research, should always outweigh the probability of harm. Finally, if there is any harm resulting from participation in the research, then there must be an offsetting and compelling benefit, either to the subject or society in general.

**Justice**— The principle of justice requires that subjects be selected fairly and that the risks and benefits of research are distributed equitably. Investigators should take precautions not to select subjects simply because of the subjects' easy availability (e.g., coworkers), their compromised position (e.g., prisoners), or because of social, racial, sexual, economic, or cultural biases institutionalized in society. Investigators should base inclusion criteria on those factors that most effectively and soundly address the research problem.

