

IRB SOP 101
Regulatory and Ethical Mandate

human subjects and for a national commission to examine ethical issues related to human subject research (i.e., the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). The Commission's final report,

, defines the ethical principles and guidelines for the protection of human subjects. Perhaps the most important contribution of _____ is its explanation of three basic ethical principles:

- Respect for persons (applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations);
- Beneficence (applied by weighing risks and benefits); and
- Justice (applied by the equitable selection of subjects).

1.4 Department of Health and Human Services (DHHS) Regulations

Federal regulations require specific protections for human subjects. In May of 1974, the Department of Health, Education, and Welfare (later renamed DHHS) codified its basic human subject protection regulations at 45 CFR 46, Subpart A. Revised in 1981, 1991, 1996 and 2005, the DHHS regulations present

