Resources

The Belmont Report and the Federal Regulations are the two most important federal documents that Institutional Review Boards must follow.

The United States Government passed the National Research Act of 1974 which set up the National Commission for the Protection of Human Subjects of Behavioral and Biomedical Research and lead to the development of the Institutional Review Board system and the codification of rules pertaining to their structure and function and to some general requirements of ethical concerns of informed consent, risk to benefit ratio and documentation issues. Ethicists from various research fields on the commission reviewed historically relevant ethical codes and statements like the Nuremburg Code and Helsinki Declaration and modern day cases of abuses like the Tuskegee Syphilis Study. The commission’s report, named after the conference center where they met, came to be known as “The Belmont Report.”

The Belmont Report

The Belmont Report outlines three basic ethical principles that underlie the US regulations and other systems of ethics in research. These principles are: Respect for Persons, Beneficence and Justice. They are outlined below.

- Respect for Persons concerns protecting a person’s autonomy and treating people with respect. It provides the basis for the requirement of obtaining informed consent from research participants.
• Beneficence requires maximizing benefits for the research project while minimizing risks to the research subjects.

• Justice ensures reasonable, non-exploitative and well-considered procedures are administered fairly (the fair distribution of costs and benefits.)

Federal Regulations

Federal regulations for the protection of human participants in research have been adopted by more than fifteen federal agencies and have thus come to be known as the “Common Rule.” The Belmont Report is the basis for the regulations. The Department of Health and Human Services (DHHS) regulations are 45 CFR 46. The Food and Drug Administration (FDA) parallel regulations are found at 21 CFR 50 and 21 CFR 56.

OHRP

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.