

Background and History of Medical Ethics

Global History:

Medical Research has been going on since prehistoric times, when one can imagine a cave man chewing on some leaves and finding that his pain went away, or his limbs went numb. The Hippocratic Oath was written about 400 B.C.E. and includes "I will follow that system of regimes which, according to my ability and judgement, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous." We can trace modern concerns about the ethical treatment of human research subjects to the Nuremberg Military Tribunal, which followed the "research" performed under Nazi Germany during World War II. The tribunal findings were codified as the Nuremberg Code in 1947. This was followed by the initial Declaration of Helsinki (1964) of the World Medical Association, which has been revised and updated several times since then.

United States History:

1953 The Clinical Center of the National Institutes of Health produced the first U.S. Federal Policy on protection of human subjects.

1962 The U.S. Food and Drug Agency began taking a role in medical research. Following disastrous thalidimide experiments, the FDA required informed consent for any funded research.

1966 The first Public Health Service policy on the Protection of Human Subjects required prospective review of human subjects research.

1968 Following the first heart transplant, Senator Walter Mondale introduced a bill to establish a commission on Health, Science and Society. The bill did not succeed. Similar resolutions were introduced in 1969, 1971, and 1973. Finally, in 1974, the National Research Act established the Commission, which met from 1974 to 1978.

1978 The Belmont Report set forth the national policy on ethics in human subjects research [The Belmont Report](#)

The Belmont Report established:

1. Boundaries between practice & research
2. Basic ethical principles
 - a. Respect for persons
 - b. Beneficence
 - c. Justice
3. Applications
 - a. Informed Consent
 - b. Assessment of Risk and Benefits
 - c. Selection of Subjects

1980 – present: Establishment of detailed procedures based upon the policies set forth in the Belmont Report. In particular there are two main sets of Federal Regulations, which detail the procedures for review of research involving human subjects:

1. [The Common Rule \(DHHS Regulations 45CFR46, as amended\)](#)
2. [FDA Regulations 21CFR56](#)
3. 1982 the World Health Organization, Council of International Organizations of Medical Sciences Proposed International Guidelines for Biomedical Research involving Human Subjects.

Philadelphia Department of Public Health

The Committee for the Protection of Human Subjects of the Philadelphia Department of Public Health began reviewing research involving human subjects in 1968. The name was changed to Institutional Review Board in May, 1994. The Health Department has endeavored to maintain adherence to the ethical principal and all relevant regulations in the protection of human research subjects.

Today, the Department has expanded its review beyond that required by Federal Regulations. The policy of the Philadelphia Department of Public Health is to require initial review of all studies by the full IRB membership. Additionally, studies involving bodies or records from the Medical Examiner's Office must be reviewed by the IRB. Referral of patients from Health Department services to studies outside of the Department also must first be reviewed by our IRB. Since the City of Philadelphia only has the one IRB, it also reviews those studies proposed using records from the City's Department of Finance regarding care of injured City employees, and studies of patients whose services are funded through the Philadelphia Department of Behavioral Health.