GLOBAL HISTORY:

Prehistoric times: Imagine a cave man chewing on some leaves and finding that his pain went away, or his limbs went numb.

About 400 B.C.: The Hippocratic Oath was written and includes “I will follow that system of regimes which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.”

1947 Nuremberg Code: 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.

1964 Declaration of Helsinki of the World Medical Association. This has since been revised and updated many times.

UNITED STATES HISTORY:

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

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


1978: The Belmont Report set forth the national policy on ethics in human subjects research.

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

**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 HISTORY**

**1968**: The Committee for the Protection of Human Subjects began reviewing research involving human subjects.

**1994**: The name was changed to Institutional Review Board.

**Assurance** – The IRB operates under a Federal Wide Assurance that it will follow all relevant regulations and the Ethical Code (Belmont Report)

**Requirements beyond Federal Regulations:**
1. Initial review of all studies by the full IRB membership.
2. Review of studies involving bodies or records from the Medical Examiner’s Office.
3. Review of studies requesting referral of patients from Health Department services to studies outside of the Department.

**Reviews for other City agencies:**
1. Studies using records from the City’s Department of Finance, Risk Manager’s Office regarding care of injured City employees
2. Studies of patients whose services are funded through the Philadelphia Department of Behavioral Health.
3. Other studies as requested by the Operating Departments.