GLOBAL HISTORY:

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: This is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA). It is widely regarded internationally as a fundamental guideline on human research ethics. It has been revised and updated 9 times, most recently in 2013.

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: Following the disastrous use of Thalidomide without adequate testing, legislation required U.S. Food and Drug Agency (FDA) approval before drugs could be marked in the U.S. The FDA began taking a role in medical research.


1973: The Tuskegee Syphilis Study, begun in 1932, was halted after public exposure and condemnation. Federal researchers had recruited and followed 400 low-income African-American men with syphilis. They did not inform the men that they were taking part in a research study, and after the discovery of syphilis, the researchers actively intervened to prevent the men from receiving treatment. Articles describing the study and the “natural history” of syphilis in these men appeared in medical and public health journals throughout the 4 decades of the study.


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

1. A definition of human subjects research (as opposed to medical practice)
2. Basic ethical principles that should govern such research
   a. Respect for persons
   b. Beneficence
   c. Justice
3. Procedural safeguards
   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**


**Philadelphia Department of Public Health History**


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:

Federal regulations of research constitute a floor, not a ceiling for ethical review. In recognition of the City’s responsibility to protect the rights and welfare of individuals we serve, Philadelphia Department of Public Health IRB policies require the following:

1. Initial review of all studies by the full IRB membership (no expedited review of new studies).
2. Review of studies involving bodies or records from the Medical Examiner’s Office (which are not classified as human subjects research under Federal regulations).
3. Review of studies requesting referral or recruitment of patients from Health Department services to studies outside of the Department (which is not regarded as engagement in research under Federal guidance).

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