

Ethical Principles

1. **The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research**. Washington, DC. U.S. Government Printing Office, 1978. DHEW Publication No. (OS) 78-0012. Reprinted in Federal Register 44 (April 18, 1979):23192. <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
2. **The Nuremburg Code**. Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council. Law No. 10, Vol 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949. <http://www.hhs.gov/ohrp/references/nurcode.htm>
3. **World Medical Association**. "Declaration of Helsinki." As amended by the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000. Revision date 09/20/01 <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>

Regulations (OHRP)

4. **45 CFR Part 46**: Code of Federal Regulations- Public Welfare: Protection of Human Subjects. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html/>
 - a. **Subpart A**: Federal Policy for the Protection of Human Subjects <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html/#subparta>
 - b. **Subpart B**: Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb>
 - c. **Subpart C**: Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>
 - d. **Subpart D**: Additional DHHS Protections for Children Involved as Subjects in Research <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html/#subpartd>

Guidance

5. **HIPAA and Protected Health Information**. <http://www.hhs.gov/ocr/privacy/>
6. DHHS Office for Human Research Protections: **OHRP IRB Guidebook** <http://www.hhs.gov/ohrp/policy/index.html>
7. **OHRP Determination Letters**. <http://www.hhs.gov/ohrp/compliance/letters/index.html>

8. Human Research Questions & Answers (OHRP).

<http://www.hhs.gov/ohrp/policy/faq/index.html>

Other Resources

Association of American Universities Task Force on Research Accountability. Report on University Protections of Human Beings Who Are the Subjects of Research. Washington, DC:AAU, 2000.

Association of American Universities Task Force on Research Accountability. Report on Individual and Institutional Financial Conflict of Interest. Washington, DC:AAU, 2001.

Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Clinical Research. Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research. Washington, DC:AAMC, 2001.

DHHS Office of Inspector General, Protecting Human Research Subjects: Status of Recommendations, OEI-01-97-00197. Washington, DC:DHHS, 2000.

DHHS Office of Inspector General, Institutional Review Boards: A Time for Reform. OEI-01-9700193. Washington, DC:DHHS, 1998.

DHHS Office of Inspector General, Institutional Review Boards: The Emergence of Independent Boards. OEI-01-97-00192. Washington, DC:DHHS, 1998.

DHHS Office of Inspector General, Institutional Review Boards: Promising Approaches. OEI-0197-00191. Washington, DC:DHHS, 1998.

DHHS Office of Inspector General, Institutional Review Boards: Their Role in Reviewing Approved Research. OEI-01-97-00190. Washington, DC:DHHS, 1998.

DHHS Office of Inspector General, Low-Volume Institutional Review Boards. OEI-01-97-00194. Washington, DC:DHHS, 1998.

DHHS Office of Inspector General. FDA Oversight of Clinical Investigators. OEI-05-99-00350. Washington, DC:DHHS, 2000.

DHHS Office of Inspector General. Recruiting Human Subjects. Pressures in Industry-Sponsored Clinical Research. OEI-01-97-00195. Washington, DC:DHHS, 2000.

DHHS Office of Inspector General. Recruiting Human Subjects. Sample Guidelines for Practice. OEI-01-97-00196. Washington, DC:DHHS, 2000.

General Accounting Office, Scientific Research: Continued Vigilance Critical to Protecting Human Subjects, GAO/HEHS-96-72. Washington, DC:GAO (1996)