ETHICS IN CLINICAL RESEARCH

Ethics: *The study of standards of conduct and moral judgments; moral philosophy.*

NUMBERG CODE – 1949

The Numberg Code was the first international document to delineate guidelines for the ethical conduct of biomedical research. It describes permissible medical experimentation on humans.

Code Specifics:
Voluntary consent must be obtained. Volunteers have the right to withdraw at any time. Experiments must provide benefit for society. Studies must be conducted to avoid unnecessary injury. The Numberg Code was largely adopted due to Nazi prisoner experiments.

DECLARATION OF HELSINKI – 1964

The Declaration of Helsinki is a set of 12 principles adopted by the World Medical Association in 1964 to guide physicians. The Declaration emphasizes the distinction between medical care which provides direct benefit to the patient and research which may or may not provide direct benefit to the patient/subject. The Declaration states that subjects must be informed of all aspects of the study including:

- Aims
- Methods
- Anticipated benefits
- Potential hazards
- Discomforts of study

THE BELMONT REPORT – 1979

The Belmont Report summarizes the ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. It states that some distinction is necessary in order to determine which studies should be reviewed by the investigational review board (IRB) to ensure the protection of human subjects.

Three basic principles:

1. **Respect for persons.** Persons should be treated as autonomous agents and those with diminished autonomy are entitled to protection. An autonomous person is one capable of deliberations about personal goals and acting upon those deliberations.
2. **Beneficence.** Do no harm and maximize possible benefits and minimize possible harms.

3. **Justice.** Requirement for fair and equitable subject selection. Treat all participants fairly with no bias.

The Belmont Report also mandated changes in the informed consent. The informed consent must disclose specific items such as risk, benefits, and alternatives. The consent form must also be in a language understandable to the subject and the consent must be voluntary with no coercion or undue influence.

Regulatory Policies Established For The Conduct Of Clinical Trials:

Guidelines have been established to protect subjects and obtain credible data and have resulted in numerous requirements. Conferences and agencies at the global, federal and local levels have adopted guidelines for human experimentation.

GLOBAL:

International Conference on Harmonization (ICH) – Guideline for Good Clinical Practice (GCP)

ICH guidelines are intended to protect and promote global public health by:

- Reducing duplicate testing of pharmaceutical products,
- Enhancing the economical use of resources during testing,
- Eliminating delays in drug development,
- Maintenance safeguards oh the quality, safety, and efficacy of new drugs and devices.

The Guidelines for Good Clinical Practice are also referred to as the “rules of research”.

FEDERAL:

The Food and Drug Administration (FDA) exists as a branch of the United States Department of Health and Human Services. FDA has been charged with regulating pharmaceutical products by:

- Facilitating the availability of safe and effective drugs,
- Keeping unsafe or ineffective drugs off the market,
- Providing understandable drug information for physicians and consumers

The mission of the FDA is accomplished through its Center for Drug Evaluation and Research (CDER). The CDER evaluates data acquired in preclinical and clinical trials prior to the marketing of new drugs and reviews data for changes in the labeling for marketed drugs.

FDA rules and guidelines are public record and are published in the Federal Register. The Federal Register is a uniform system for making regulatory and legal notices available to the public. It provides accountability of legislative and regulatory activities within the federal government.

Permanent records are coded in the Code of Federal Regulation (CFR). Standards of practice are recorded on the CFR which addresses requirement for clinical research. They are recorded in the following areas:

Title 21: Food and drug
Title 45: Public Welfare

LOCAL:

Investigation Review Board (IRB).

The investment review board may be a local board or may be a central IRB. The IRB's responsibility with clinical research is to protect the rights, safety and well-being of human subjects in clinical trials by:

- Reviewing protocols and consents,
- Providing approval,
- Monitoring progress.

The IRB is also a resource for patients participating in clinical trials.

* SEE OFFICE TRAINING MANUAL FOR COPY OF:

1. Nuremberg Code
2. World Medical Association Declaration of Helsinki
3. The Belmont Report
4. IHC Guideline for Good Clinical Practice