

## **THE BELMONT REPORT**

When the National Research Act was signed into law on July 12, 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. The Commission was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that research is conducted in accordance with those principles. During their discussions the Commission considered the boundaries between medical practice and research, the role of assessment of risk-benefit in the determination of the appropriateness of research involving human subjects, guidelines for the selection of human subjects and the nature and definition of informed consent. The Belmont Report thus attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations in February 1976. The report itself does not make specific recommendations for administrative action, but rather its objective is to provide an analytical framework that will guide the resolution of ethical problems arising during research involving human subjects.

### **BASIC ETHICAL PRINCIPLES:**

- ❖ **Respect for Persons** ~ all volunteers are treated as individuals and are entitled to protection.
  - **Informed Consent:** each subject to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them
    - **Information:** The extent and nature of the information should be such that persons can decide whether they wish to participate in the furthering of knowledge. That is to say, consenting individuals are aware that the procedure is neither necessary for their care nor perhaps fully understood, and they understand clearly the range of the risks.
    - **Comprehension:** The ability of a subject to understand is a function of intelligence, rationality, maturity and language and therefore it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information.
    - **Voluntariness:** The agreement to participate in research is considered a valid consent, if and only if voluntarily given under conditions free of coercion and undue influence.
- ❖ **Beneficence**
  - Do Not Harm
  - Maximize possible benefits minimize possible harms
  - Assessment of Risks and Benefits
- ❖ **Justice** ~ fairness in distribution
  - To each person an equal share
  - To each person according to individual need
  - To each person according to individual contribution
  - To each person according to merit