

## **Training Material for - The Belmont Report**

### ***Institutional Training for Research Involving Human Subjects***

As a result of the revelations of serious abuses of human research subjects during the Nuremberg War Crimes Trials, The Nuremberg Code was formulated. It set standards for physicians and scientists using human subjects and was the Prototype code for human subjects research. Immediately after World War II, many questions were raised about the ethical propriety of use of human subjects in biomedical research. In July 1974, Congress passed The National Research Extension Act (PL 93-348), that created the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. “In 1979, the Commission produced The Belmont Report, a statement of ethical principles and guidelines that assists in resolving the ethical problems that surround the conduct of research with human subjects”

The Report defined boundaries between PRACTICE and RESEARCH. Practice was defined as “interventions designed solely to enhance the well-being of an individual that has a reasonable expectation of success.” Research was defined as an activity designed to test a hypothesis, draw conclusions, or develop or contribute to generalized knowledge, which uses a protocol format with objective procedures.

The Belmont Report developed three Basic Ethical Principles: Respect For Persons, Beneficence, and Justice.

#### ***Respect for Persons***

This first principle incorporates at least two Ethical Convictions: that individuals should be treated as autonomous agents, and that persons with diminished autonomy are entitled to autonomy. It also incorporates at least two Moral Requirements: a requirement to acknowledge autonomy, and a requirement to protect those with diminished autonomy. An Autonomous individual is defined as being capable of self-deliberation and acting under direction of such self-deliberation. Not every individual is capable of self-determination. The extent of protection afforded certain individuals is dependent upon the risk of harm and the likelihood of benefit.

#### ***Beneficence***

This second principle of the Belmont Report translates into two strict actions:

1. Do no harm
2. Maximize possible benefits, and minimize possible harms

THE DILEMMA - deciding when it is justifiable to seek certain benefits despite the risks, and when benefits should be foregone because of the risks.

#### ***Justice***

The Belmont Report considers the third principle of “Justice.” Who should receive the benefits of research - and who should bear its burdens?? The selection of research subjects should be scrutinized in order to determine whether some classes (welfare patients, particular racial and ethnic minorities, or institutionalized persons) are selected because of their easy availability, compromised position, or manipulability rather than for reasons related to the problem.

During the 19th and early 20th century, the burden of serving as research subjects fell largely upon poor ward patients, while the benefits of knowledge and improved medical care flowed primarily to private patients. This violated the basic ethical principle of Justice. Practical application of the three Basic Ethical Principles of The Belmont Report leads to consideration of the following requirements: Informed Consent, Risk/Benefit Assessment, and Selection of Subjects

### ***Informed Consent***

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall, or shall not happen to them. This opportunity is provided when adequate standards of informed consent are met. The Consent Process contains three elements: Information, Comprehension, and Voluntariness

Information is the first of the three elements of the informed consent process. Specific items for disclosure generally include the research procedure, the purposes of the procedure, the risks and anticipated benefits, alternative procedures where appropriate, the provision to ask questions, and the freedom to withdraw at any time.

Comprehension is the second of the three elements of the informed consent process. It is critical that the subject understand the information conveyed. Since the ability to understand is a function of intelligence, maturity, language, it is necessary to adapt the presentation of information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information.

Voluntariness is the third of the three elements of the informed consent process. Agreement to participate in research must be secured under conditions free of coercion and/or undue influence. Coercion is defined as an overt threat of harm to obtain compliance. Undue Influence is defined as excessive, unwarranted, inappropriate, or improper reward to obtain compliance, especially with vulnerable subjects.

### ***Assessment of Risks and Benefits***

This process presents both an opportunity and a responsibility to gather systematic and comprehensive information about the proposed research. For different players, assessment of risk/benefit means different things. For the investigator, it is a means to examine whether research is properly designed. For the IRB, it is a means for determining whether risk to subjects are justified. For the participant, it is a means for assisting the determination of whether or not to participate. The requirement that research be justified on the basis of a favorable Risk/Benefit assessment relates to the ethical principle of Beneficence.

RISK refers to the possibility that harm may occur. Discussions of risk deal in "probabilities." BENEFIT implies something of positive value related to health or welfare. Benefits do not deal in probabilities. Risk/Benefit assessments are concerned with probabilities of possible harm, and with magnitudes of anticipated benefits. Risks and Benefits must be "Balanced" and in a "Favorable Ratio." This requires a systematic nonarbitrary analysis of risks and benefits insofar as possible.

There should be a systematic determination of the validity of the presuppositions of the research; of the nature, probability, and magnitude of risk that the investigator's estimate of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

There are several Important factors in the Assessment of the JUSTIFIABILITY of research. First, brutal or inhumane treatment of human subjects is never justified. Second, risks should be reduced to only those necessary to achieve the research objective. Third, researchers should consider alternatives, including the elimination of human subjects from the research design. Fourth, when significant risk is involved, strong justification is demanded. Fifth, when vulnerable subjects are involved, appropriateness of their inclusion must be demonstrated. Last, any relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the consent process.

### ***Selection of Subjects***

The final practical application of the ethical principles of the Belmont Report is Selection of Subjects. The principle of Justice gives rise to the moral requirements that there be fair procedures and outcomes in the selection of research subjects.

The Principle of Justice is relevant to the Selection of Subjects at two levels - Individual and Social Justice. In Individual Justice researchers must exhibit fairness and not offer potentially beneficial research to only some patients who are in their favor, or select only “undesirable” persons for “risky” research. Social Justice requires that distinction be drawn between classes based upon the ability of classes to bear burden of research, not placing further burden on already burdened persons. This means that there may be an order of preference for classes, i.e. adults before children, and that some classes (prisoners, mentally infirm, etc.) may be involved only in certain conditions.

When proposed research involves risks without a therapeutic component, less burdened classes than the infirm and/or institutionalized should be asked to accept the risks of the research - except where the research is directly related to specific conditions of the class involved. Certain groups such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may be continually sought because of their availability in settings where research is conducted. They should be protected against being involved in research for administrative convenience, or their socioeconomic condition.

### ***Summary of Important Points in The Belmont Report***

1. The Belmont Report is a statement of ethical principles and guidelines that assists in resolving the ethical problems that surround the conduct of research with human subjects.

2. The three key ethical principles that are the cornerstone of The Belmont Report are: Respect for Persons, Beneficence, and Justice.

3. The investigator and the IRB must carefully evaluate the Risk/Benefit ratio to ensure that a proposed study has a reasonable chance for benefits in relation to probable risks.

4. Agreement to participate in research must be completely voluntary, and secured under conditions free of coercion and/or undue influence.

5. A key concept of The Belmont Report is the special consideration for and protection of potentially vulnerable subject populations - children, prisoners, certain racial minorities, those with diminished autonomy, etc.

6. The Belmont Report is a key reference document influencing federal regulations and guidelines for research using human subjects.