Basic Principles of the Belmont Report

In the Nuremberg war crime trials after World War II, Nazi biomedical researchers were prosecuted for their abuses against prisoners in concentration camps. A proper set of standards for judging the physicians and scientists who had conducted experiments on the prisoners was drawn up by the presiding international tribunal. The basic ethics of the Nuremberg Code continue to serve as a cornerstone for modern regulations regarding the use of human participants in experimentation. **Its principles emphasize a profound respect for the voluntary nature of research participation, the idea of true informed consent, and the personal ethical responsibilities of the investigator to ensure human welfare.**

In 1979, the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* was published in the United States to provide a succinct description of the mandate for review of research involving human research participants. Regulation and guidelines concerning the use of human research participants in the U.S., and increasingly so in other countries, are based on the following fundamental elements excerpted from the Belmont Report:

Respect for Persons has at least two ethical considerations. The first is that the individual human research participant be treated as an autonomous being—a person who makes decisions or deliberates for herself about personal goals and then acts upon them. The second is that those persons who are not able to make and carry out decisions for themselves, such as children or sick people or those who have a mental disorder, must be protected from coercion by others and from activities that harm them. How much to protect them is related to the risk of harm and likelihood of benefit to them. **In research, respect for persons demands that participants enter into a research program voluntarily and with good information about the research goals.**

Beneficence has to do with doing good to the individual. In the Belmont Report, beneficence is understood in a stronger sense, as an obligation, i.e., to do no harm and to "maximize possible benefits and minimize possible harms" to the individual research participant. "Do no harm" is a Hippocratic principle of medical ethics though its extension into research implies that "one should not injure one person regardless of the benefits that might come to others." But sometimes you cannot know that something is harmful until you try it and in the process of trying, or experimentation, persons may be exposed to risk of harm. The Hippocratic oath also requires that physicians benefit patients "according to their best judgment," but again learning what will benefit may mean exposing a person to risk.

The principle of beneficence obligates both society and the individual investigator. Society has to give forethought to the longer term benefits and risks that result from increased knowledge and from the development of novel new therapeutic devices or

procedures that are the outcome of research. **Investigators and their institutions have to plan to maximize benefits and minimize risks.**

Justice, in this report, refers to the benefits and harms to individual subjects of research. In the 19th and early 20th century hospitals in America, the burdens of experimentation fell upon the poor charity patients while the rewards of the improved medical care went primarily to the rich private patients. The Nazi researchers and concentration camp prisoners provides another good example of injustice. The benefits and burdens of research should be justly distributed. The selection of research participants needs to be constantly monitored to determine whether some pools of participants are being systematically selected from simply because they are easily available or vulnerable or easy to manipulate, rather than chosen for reasons directly related to the research problem being studied.

Applications for comprehensive ethical principles in research involving human participants

Informed consent

A critical component of respecting human participants is the **informed consent process**. The consent document is a written summary of the information that should be provided to the participant. Many investigators use it as a guide for the verbal explanation of the study. The participant's signature on the form shows agreement to participate in a study, but that is only one part of the consent process. The entire informed consent process involves:

1) giving a participant adequate information about the study,
2) providing adequate opportunity for the participant to consider all options, responding to the participant's questions,
3) ensuring that the participant has comprehended this information,
4) obtaining the participant's voluntary agreement to participate, and
5) continuing to provide information as the participant or situation requires.

In the case of subjects whose ability to understand might be limited, i.e., children, mentally disabled patients or those who are very ill, special provision may have to be made. With these groups, often permission must be sought from a third party who would be in a position to understand the incompetent participant's situation and act in their best interest. This third person should be able to follow the research and be able to withdraw the participant if it appears to be in the best interest for the individual.

To summarize: the informed consent process must allow human participants, as much as they are able, to be given opportunity to choose what will or will not happen to

them. The consent process must include information to the participant about the research; the participant must understand the information and volunteer rather then be coerced into participation.

Assessment of Risks and Benefits

Assessing risks and benefits means the researcher needs to assemble all data that explains why the research will obtain the benefits that are sought by the research project. The review committee of the researcher's sponsoring institution, upon review of the collected data, can decide whether the risks to the subjects are justified. Prospective participant can determine whether or not to participate.

The term "risk" refers to the possibility that harm might occur. There are many kinds of risks, such as psychological, physical, legal, social and economic hardship. The term "benefit" in the research context refers to something positive as related to health or welfare. Risk and benefits affect not only individual partcipants, but also their families and society at large. Importantly, in the past regulations about human subjects, **the risk to participants has been outweighed by the sum of both the anticipated benefit to participants, and the anticipated benefit to society in the form of new knowledge to be gained by the research.**

Selection of Participants

The principle of justice—that benefits and risks of research be distributed fairly. Researchers are not just if they only select disadvantages persons for risky research or only provide beneficial research to groups they favor. Special classes of injustice arise when participants are drawn from vulnerable populations, like those institutionalized or incarcerated in prisons, racial minorities, economically disadvantaged or the very sick.

Ethical Principals for Research	Applications of Ethical Principles for Research
Respect for Persons · Individuals should be treated as autonomous agents · Persons with diminished autonomy are entitled to protection.	**Informed Consent** · Volunteer research participants, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them · The consent process must include three elements: o Information, o Comprehension, and o Voluntary participation
Beneficence · Human participants should not be harmed · Research should maximize possible benefits and minimize possible risks	**Assessment of risks and benefits** · The nature and scope of risks and benefits must be assessed in a systematic way
Justice · The benefits and risks of research must be distributed fairly	**Selection of participants** · There must be fair procedures and outcomes in the selection of research participants

Fig. 1 Basic ethical principles and applications as outlined in the Belmont Report