

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

GUIDING PRINCIPLES: Summary

1. Respect for Persons

A. Autonomy:

Personal capacity and right to consider alternatives, make choices, and act without undue influence or interference by others. The principle of Autonomy underlies “Informed Consent”.

B. Respect for Persons with diminished autonomy:

An ethical principle requiring that individual autonomy be respected and that special provisions be made to protect the rights of persons with diminished autonomy.

2. Beneficence:

An ethical principle that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated benefits and minimizing possible risks of harm.

(Note: Incorrectly simplified to: “greatest good for the greatest number”.)

3. Justice:

An ethical principle requiring fairness in the distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Background

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote the report entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, commonly called the “Belmont Report.” In this report, the Commission identified and described the basic ethical principles that underlie research. The Commission considered the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine in order to “know what activities ought to undergo review for the protection of human subjects of research.” The report also describes the assessment of risk/benefit criteria in the determination of appropriateness of research on participants, appropriate guidelines for this assessment, and the nature and definition of informed consent. The three fundamental ethical principles that guide the ethical conduct of research involving human participants are:

1. Respect for Persons

The principle of respect for persons incorporates at least two ethical standards:

A. Individuals should be treated as autonomous agents.

“An autonomous person is an individual capable of deliberation about personal goals and of acting under such deliberation. To respect autonomy is to give weight to the autonomous person’s considered opinions and choices while refraining from obstructing his or her actions”

(Belmont Report).

Prospective research participants must be given the information they need to determine whether or not to participate in a study. There should be no pressure to participate and ample time to decide. Respect for persons demands that participants enter into the research voluntarily and with adequate information. This is called *informed consent*.

B. Persons with diminished autonomy may need additional protections.

Special provision may need to be made when comprehension is severely limited or when a class of participants is considered incapable of informed decision making (such as with children or people with severe developmental disorders or dementias). Even for these persons, however, respect requires giving them the opportunity to choose, to the extent they are able, whether or not to participate in research activities. In some cases, respect for persons may require seeking the permission of other parties, such as a parent or legal guardian. The judgment that someone lacks autonomy should be periodically reevaluated and may vary in different situations.

2. Beneficence

Human participants are treated in an ethical manner not only by respecting their decision and protecting them from harm, but also by making efforts to secure their well-being. The principle of *beneficence* obligates the researcher to maximize possible benefits and minimize possible harm.

The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite inherent harms or risks. Balancing risks and benefits is an important consideration. The goal of much research is societal benefit; however, in the interest of securing societal benefits; no individual shall be intentionally injured.

3. Justice

The ethical considerations of risks versus benefits leads to the question of *justice*. This principle requires that participants be treated fairly and involves questions such as: Who should bear the risks of research, and who should receive its benefits?

Justice is a difficult and complex ethical issue. Attempts must be made at all times in a study to distribute the risks and benefits fairly and without bias. Also, unless there is clear justification, research should not involve persons from groups that are unlikely to benefit from subsequent applications of the research. The concept of justice may be questioned when deciding who will be given an opportunity to participate, who will be excluded, and the reasons for exclusion. When making such decisions, the researcher must ask: Are some classes of persons being selected simply because of their availability, their compromised position, or their vulnerability—rather than for reasons directly related to the problem being studied?