Hippocratic Oath (5th century B.C.)

The Hippocratic Oath is the oldest existing guidance for ethical clinical practice. Recited by most graduating medical students to this day, it stipulates that physicians should avoid harming the patient, that patient confidentiality must be respected, and that physicians should not perform procedures for which they are not qualified. The guiding principle of Hippocrates’ writing on the physician’s responsibility to the patient is, “First, do no harm.”

Three Fundamental Principles of Human Research Ethics

Respect for persons, beneficence, and justice. These principles are considered to be universal—they apply everywhere in the world. These principles do not have national, cultural, legal, or economic boundaries. Everyone involved in human research studies should understand and follow these principles.

Respect for Persons—Recognition of the research subject as an autonomous, unique, and free individual. It means that we recognize that each person has the right and capacity to make her or his own decisions.

Beneficence—Literally the quality of doing or producing good (Merriam-Webster Dictionary). In research, the principle of beneficence makes the researcher responsible for the physical, mental, and social well-being of the research participant.

Justice—Justice requires the fair and equal distribution of benefits and risks of participation in a research study. Recruitment and selection of participants must be done in a fair and equal manner. Justice forbids exposing one group of people to the risks of the research solely for the benefit of another group. Community representatives have the responsibility to ensure that community participation in a research study is justified.

Non-maleficence

The commitment to avoid risks or reduce them as much as possible in line with the Hippocratic physician’s commitment to avoid harm to the patient.

Nuremburg Code (1946)

Written after the discovery of cruel Nazi experiments on concentration camp prisoners. It states that “voluntary informed consent is absolutely necessary” in research on human subjects.
Thapa, 2008

**Declaration of Helsinki (1964 & 2001)**

- Regularly cited as a reference in most national or international guidelines and is considered by many to be the first international standard for biomedical research.
- Distinguishes research that is “therapeutic” from research that is not of immediate benefit to subjects\(^1\)
- Gives special attention to the importance of written informed consent.
- Highlights physician’s duties, not just patient rights
- The version revised in 2001 also states that "medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research."

**Belmont Report (1978)**

Produced by the U.S National Commission for the Protection of Human Subjects after the American public became aware of the Tuskegee Syphilis Study, in which 399 poor black sharecroppers were denied treatment for syphilis by physicians of the U.S. Public Health Service from 1932 to 1972. The report advocated *respect for persons, beneficence, and justice* as the fundamental principles for the ethical conduct of research involving human participants. The current federal regulations for the conduct of research in the United States are derived from the ethical principles of the Belmont Report.

**Council for International Organizations of Medical Sciences Guidelines (CIOMS)**

The Guidelines consist of 21 specific guidelines, each followed by interpretative commentaries. Some guidelines of special interest to community representatives are:

- Establishing Ethical review committees
- Obtaining informed consent: essential information for prospective research subjects
- Benefits for participants and their communities
- Provision of health care services
- Distribution of the burdens and benefits

The CIOMS Guidelines are very influential and have been widely disseminated. They are frequently used as a reference for developing national or local guidelines.

**Local Guidelines**

In many developing countries, an urgent need remains for local-level regulations and the establishment and support of supervising mechanisms. Community representatives should bring the importance of this issue to their respective local government bodies.

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\(^1\) Therapeutic research investigates the treatments of diseases and disorders.
**Ethics Committee/Institutional Review Board**

An ethics committee is a group of people from different backgrounds that conducts an independent review of proposed studies on human participants. All international regulations require the review and approval of human research studies by an independent and qualified ethics committee prior to initiation.

**Informed consent**

Informed consent is essential to research ethics. The CIOMS Guidelines have defined informed consent as: "Consent given by a competent individual who: 1) Has received the necessary information (verbally and in writing); 2) Has adequately understood the information; 3) After considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation."

A proper informed consent process includes the following:

- A description of research procedures including: who, what, why, where, and when
- A description of risks
- A description of benefits
- A discussion of alternatives to participation
- An explanation of confidentiality
- A discussion of compensation for injuries or health problems resulting from study
- Contacts: whom to contact with questions and concerns about the research
- An explanation of voluntary participation and withdrawal
- Subjects receive copy of consent form
- Consent process explained in language the respondent understands

When pursuing research in developing countries, researchers should go to great lengths to ensure that participants fully understand the procedures and purpose of the experiment.

**Vulnerable Persons**

Groups traditionally viewed as vulnerable include minors, pregnant women, prisoners, and persons with mental disabilities. In recent years, attention has been given to other types of vulnerable persons (including but not limited to):

- **Persons with limited education or illiterate persons** who may find it difficult to understand informed consent information.
- Persons with few economic resources who may have **limited access to health services** and may see their participation in a research study as the only opportunity to obtain needed health care.
- **Sex workers or homosexuals.**
- **Women** in some settings. For example, some women must ask their husbands before consenting to participate in a study.
- **Drug users** or others who engage in illegal activities.
Vulnerable persons can still participate in a research study; however, they need special protections. Researchers and community representatives should understand that even small gifts or tokens to research participants can influence decisions, making persons vulnerable.

**Standard of Care Debate**

In clinical trials, researchers must provide health care to participants. This debate concerns the level of care that should be provided, given that participants would have little to no access to western medical care absent the study. Some experts state that less than best practice can be used when it is “ethically appropriate and has the potential to provide sufficient benefit for the host communities.” Institutional review boards play a key role in determining what is permissible.

**Society for Adolescent Medicine (SAM) Guidelines**

SAM is an American organization of health professionals that promotes adolescent health. Their guidelines for ethical research on adolescents emphasize that:

- When the study has less than minimal risk, “parental permission may be waived, provided that the IRB has found that” the confidentiality of participants is ensured, informed consent of adolescents is obtained, adolescents are encouraged to seek support of a parent or other caring adult, and adolescents may seek confidential assistance after the study is complete.
- When the study has greater than minimal risk, but the potential of direct benefit, adolescents should be encouraged to obtain parental permission. Adolescents may consent without parental permission when: confidentiality and privacy is ensured, informed consent is obtained, and a clinical professional not associated with the study provides emotional support to the adolescent. This adult need not have a formal, legal role in the process.
- When the study has greater than minimal risk, no potential of direct benefit, but potential to yield generalizable information about the adolescent’s medical disorder, parental consent and adolescent assent should be required.
- When research in the United States “offers an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of minor adolescents,” the Secretary of the U.S. Health and Human Services Department must consult with a panel of experts. These should be handled on a case-by-case basis.

**Assent versus Consent in the Treatment Context**

Where adolescents are legally incapable of providing consent or lack the proper maturity, may still have decision-making power through the provision of assent. Assent refers to the adolescent’s willingness or unwillingness to undergo medical treatment. Even when legal guardians give legal consent, minors may be able to refuse treatment or express their preference for a certain type of treatment.
The Role of the Community in Research

In recent years, there has been growing recognition that the traditional informed consent process does not sufficiently address the concerns of the community. Researchers may also need to acknowledge the role of family members. While family members should not be able to veto participation, resources should be made available for them.

Enhanced Informed Consent

An enhanced informed consent model includes greater collaboration with the community through community advisory boards. Also, in order to best protect participants in certain developing country contexts, researchers should follow the informed consent process during preenrollment, enrollment, and postenrollment, at both the individual and community levels.

Cultural Factors that Should Inform Ethical Research

Researchers and communities may have very different conceptions of disease and health, which complicates the informed consent and research process. In addition to using the correct language, researchers must be careful to use correct vocabulary and idiomatic expressions for the local setting and age level of the target group. Documenting the local lexicon can prove beneficial for other researchers in the area.

Key References


Council of International Organizations of Medical Sciences (CIOMS) in collaboration with WHO, *International Ethical Guidelines for Epidemiological Studies (2008)*


