Chapter 2
Ethics in health research

2.1 Introduction

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation

International Covenant on Civil and Political Rights, Article 7, 1966

A number of developments have brought the subject of ethics in medical research to the front line of concerns of the health profession and the society at large. These include a major expansion in health research, the significant public investment in research, the increasing need for experimentation on human subjects, publicized cases of ethical violation, internationalization of research, and the expanding role of private industry. This century has witnessed a major expansion in health research. Medical research has opened new areas for investigation, for which society has not yet been fully prepared morally, legally and socially. These include areas such as organ transplantation, assisted conception, advances in fertility regulation, and the new era of genomics. Societies make a significant investment in health research. They have become shareholders and thus have a say in how their investment is made.

Advancement of medical knowledge depends, to a large extent, on expansion of research involving experimentation on human subjects. With the increasing acceptance and appreciation of individual human rights, and of the need to respect and protect them, it is not acceptable that the welfare and the respect of the individuals be compromised in the pursuit of benefits that may accrue to science and society. Instances of violation of ethical principles for the sake of advancement of science have occurred. The most outrageous cases were revealed in the Nuremberg trials after the Second World War. These resulted in the elaboration of the Nuremberg Code in 1947, for regulating experimentation on human subjects. The medical profession then took charge and the World Medical Association, starting in 1964, developed, adopted and updated the Helsinki Declarations which today provide guidance to the medical research community (Annex 1).

Internationalization has been a recent phenomenon in medical research. Research now knows no national frontiers. There is a need for agreement on the basic values that
govern medical research, so that the same standards apply to subjects participating in the same research in different countries. It is feared, sometimes for good reason, that advantage may be taken of countries that do not have, or do not enforce, high ethical standards, in order to advance medical knowledge, and particularly if the benefit will go primarily to other populations.

Medical research is now a major investment for private industry. Economic gains are anticipated. The strong drive to make health research an engine of economic development runs the risk of pushing research beyond acceptable ethical standards.

This chapter provides only a brief general introduction of the subject of ethics in health research. Ethical considerations are discussed in more detail in subsequent chapters dealing with what research to do, planning of the research, writing the research protocol, submitting a research proposal, implementing the research, as well publication ethics.

### 2.2 General ethical principles

Ethics are principles of right conduct. There are generally no disagreements on the ethical principles in themselves, since they represent basic human values. There can, however, be differences on how they are interpreted and implemented in specific cases. Basic principles include beneficence, non-maleficence, respect and justice.

Where research involves experimentation on human subjects, every effort should be made to maximize the benefits to the subjects (beneficence), and the subjects should suffer no harm (non-maleficence). The principle of respect implies that participation in the research should be completely voluntary and based on informed consent. Where research involves collection of data on individuals, privacy should be protected by ensuring confidentiality. Respect to the community means respecting its values and having its approval for the research. The principle of justice (distributive justice) implies that participation in the research should correlate with expected benefits. No population group should carry an undue burden of research for the benefit of another group.

Apart from the basic principles of beneficence (non-maleficence), respect and distributive justice, other principles also apply. Where research involves experimentation on animals, mercy is an ethical imperative. For research in general, medical or non-medical, honesty is an indispensable value. International ethical guidelines for biomedical research involving human subjects have been issued by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization. The latest edition was issued in 2000 (Annex 2).
2.3 Responsibility for ethics in health research

Responsibility for ensuring that ethical standards are observed in research rests collectively with the investigators, research institutions, national drug regulatory agencies, editors of medical journals, and funding agencies and organizations. Ethical approval by one does not relieve the others of responsibility.

- Investigators: The primary and ultimate responsibility rests with the investigators who should, as a part of their training, be made aware of and sensitive to the ethical imperatives in research. No research protocol is complete or acceptable if it does not discuss the ethical aspects of a study involving human subjects or experimental animals.

- Research institution: The research institution is responsible for the ethical quality of the research performed by its staff and in its facilities. Any institution involved in research on human subjects should have an institutional ethics review committee. The committee acts as a gathering of the investigators’ peers and others to provide advice on ethical aspects of the study and to approve it or disapprove it on behalf of the institution. The membership may include other health professionals, particularly nurses, as well as laymen qualified to represent the community’s cultural and moral values. The committee should be completely independent from the investigators. Any member with a direct interest in a proposal should not participate in its assessment. The next section provides more information on ethics committees.

- National Drug Regulatory Agency: New drugs or devices that are not yet approved in the country should not be used on human subjects without approval being obtained for their use under the conditions of the study.

- Editors of medical journals: Reports of research not complying with ethical standards should not be accepted for publication.

- Funding agencies and organizations: No research proposal should be funded by a national or international agency unless it has clearly outlined the ethical aspects of the study and has provided assurances that ethical principles will be observed, including, as appropriate, the approval of an institutional review committee.

2.4 Ethics committees

Countries and institutions should establish ethical review systems to ensure the protection of potential research participants and contribute to the highest attainable quality in the science and ethics of health research. Ethics committees should be established, as appropriate, at the national, regional and institutional levels.
The World Health Organization has issued operational guidelines for ethics committees that review biomedical research, outlining their role, how they can be constituted, procedure for submitting an application, elements for review, decision-making, follow-up, and documentation and archiving (WHO, 2000). The elements of ethical review include scientific design and conduct of the study, recruitment, care and protection of research participants, protection of participant confidentiality, informed consent process and community considerations. Some aspects of the work of ethics committees need to be highlighted.

- Ethics committees should be so constituted as to ensure the competent review and evaluation of all ethical aspects of the research projects they receive and to ensure that their task can be executed free from any bias and influence that could affect their independence.

- Ethics committees should be multidisciplinary and multi-sectoral in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and concerns of the community.

- Ethics committees should be established in accordance with the applicable laws and regulations of the country and in accordance with the values and principles of the communities they serve.

- Ethics committees should establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the committee, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of the secretariat, internal procedures and quorum requirements. They should act in accordance with their written operating procedures.

It may be helpful to summarize the activities of the ethics committees in a regular (annual) report.

2.5 Ethical considerations throughout the research process

The research process begins with the choice of the research topic, followed by selection of the appropriate research design, development of the research protocol, writing and submitting a research proposal for funding, implementing the study, description and analysis of the research results, interpretation of the research results, and finally communicating the research, including its publication. Ethical considerations apply throughout the research process, and will be discussed in the relevant chapters. The objective of this approach is to demonstrate that ethical considerations are integral components of the research process, and are not a subject to be discussed separately. In fact, scientific assessment of the planned research is an important part of the ethical
review process. It is unethical to expose subjects to research that is not scientifically sound, is not performed by qualified investigators in qualified facilities, and is not likely to provide valid scientific answers.

References and additional sources of information


*Research ethics training curriculum.* [CD-ROM teaching aid appropriate for international biomedical and social science researchers]. Family Health International, 2001. (E-mail: publications@fhi.org).


