

Recent Publications

International guidelines for biomedical research

For many years, the Council for International Organizations of Medical Sciences (CIOMS) has provided a forum for discussing moral and ethical issues that arise in the application of new scientific and technological knowledge to the practice of medicine. An important landmark in this involvement was the appearance in 1982 of *Proposed international guidelines for biomedical research involving human subjects*. This was the product of an extensive consultative process to determine how the fundamental principles embodied in the World Medical Association's Declaration of Helsinki can be effectively applied, particularly in developing countries, taking into account socioeconomic circumstances, national legislation and administrative arrangements.

The proposed guidelines were extensively distributed to ministries of health, medical research councils, medical faculties, relevant nongovernmental organizations, medical journals and research-based pharmaceutical companies. A subsequent survey showed that they have been widely used throughout the world, but that they merited updating, particularly with reference to ethical issues raised by large-scale trials of vaccines and drugs, transnational research, and experimentation involving vulnerable population groups. A specific matter that required consideration *de novo* was the prospect of field trials of vaccines and drugs to control AIDS.

In a broader context, it was recognized that special attention needed to be directed to epidemiological studies on account of the greatly increased capacity that now exists for such research as a result of computer technology, and the inevitable tension that this capacity has created between the rights and freedom of the individual and the needs of society. These concerns, it was felt, would best be

met by preparing a separate publication, *International guidelines for ethical review of epidemiological studies*. Such guidelines cannot resolve all the moral ambiguities that are encountered in everyday epidemiological research and practice. None the less, by defining and examining the issues, they conduce to high professional standards both in regard to human attitudes and quality of research. They also assist countries to develop relevant national policy, adopt standards for their specific national needs, and establish adequate mechanisms to review the ethical aspects of planned studies.

More recently, with the same general objectives in focus, CIOMS has published its *International ethical guidelines for biomedical research involving human subjects*. These reflect the paramount concern for vigilance in protecting the rights and welfare of research subjects, particularly as these relate to vulnerable individuals or groups. Addressed to the biomedical research community, ethics review committees, and sponsors, the guidelines address three main issues: informed consent of prospective subjects, the process of peer review, and the obligations of sponsors, particularly in the case of externally sponsored research.

Extensive revision has been undertaken of those sections of the initial guidelines concerned with informed consent, research undertaken in undeveloped communities, exclusion of pregnant and nursing women, confidentiality and compensation for injury. The guidelines do not attempt, however, to address every contentious issue. Certain areas of research entirely escape consideration: these include human genetic research, and research involving fetuses and fetal tissue. Discussion of these topics, it was felt, will remain premature within the context of a global guideline for as long as fundamental national differences in attitudes to such research continue to prevail.

International Guidelines for Ethical Review of Epidemiological Studies. Council for International Organizations of Medical Sciences (CIOMS), Geneva, 1991, ISBN 92 9036 048 8

International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organizations of Medical Sciences (CIOMS), Geneva, 1993, ISBN 92 9036 056 9

^{*} World Medical Association Declaration of Helsinki. Recommendations guiding physicians in biomedical research involving human subjects (as most recently amended during the 41st World Medical Assembly, Hong Kong, September 1989).