



United Nations Educational, Scientific and Cultural Organisation
Organisation des Nations Unies pour l'éducation, la science et la culture



*International Bioethics
Committee (IBC)*

*Comité international
de bioéthique (CIB)*

Distribution: limited

SHS/EST/CIB-EXTR/05/CONF.202/2
Paris, 9 February 2005
Original : English

Preliminary Draft Declaration on Universal Norms on Bioethics

This Preliminary Draft Declaration on Universal Norms on Bioethics was finalized by the International Bioethics Committee (IBC) at its Extraordinary Session on 28 January 2005 after six meetings of its Drafting Group held between April and December 2004, three sessions of IBC (April 2004, August 2004, January 2005), two written consultations (January-March 2004 and October-December 2004), numerous consultations at international, regional and national levels (including within the framework of the UN Interagency Committee on Bioethics), a session of the Intergovernmental Bioethics Committee (IGBC) and a joint session of IBC and IGBC (January 2005).

PRELIMINARY DRAFT DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

Recommended title:

Universal Declaration on Bioethics and Human Rights

The General Conference,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment; to perceive injustice; to avoid danger; to assume responsibility; to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the inherent dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for the human species and for the biosphere,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Also recalling the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement

and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Bearing in mind international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002,

Considering that, by virtue of its Constitution, it is incumbent upon UNESCO to promote the democratic principles of the dignity, equality and respect of human beings and to reject any doctrine of inequality, and that this constitutes a duty which all nations must fulfil in a spirit of mutual assistance,

Considering also UNESCO's role in developing universal principles based on shared ethical values to guide scientific and technological development and social transformation, in order to identify emerging challenges in science and technology taking into account the responsibility of the present generation towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere and that they have responsibilities and duties towards each other and towards other forms of life,

Recognizing that scientific and technological developments have been, and can be, of great benefit to humankind in increasing *inter alia* life expectancy and improving quality of life and emphasizing that such developments should always promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the inherent dignity of the human person and the universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that bioethical issues may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, is the common heritage of humanity, but emphasizing that it may not be invoked to contravene fundamental human rights and freedoms,

Convinced that ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play today a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the need for a new approach to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account in particular the special needs of developing countries,

Proclaims the principles that follow and adopts the present Declaration.

GENERAL PROVISIONS

Article 1 – Use of Terms

For the purpose of this Declaration:

- (i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;
- (ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and
- (iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.

Article 2 – Scope

The principles set out in this Declaration apply as appropriate and relevant:

- (i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and
- (ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.

Article 3 – Aims

The aims of this Declaration are:

- (i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;
- (ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;
- (iii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;
- (iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists,

theologians and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;

- (v) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
- (vi) to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and
- (vii) to safeguard and promote the interests of the present and future generations.

PRINCIPLES

Article 4 – Human Dignity and Human Rights

- a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms;
- b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society.

Article 5 – Equality, Justice and Equity

Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.

Article 6 – Benefit and Harm

Any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice.

Article 7 – Respect for Cultural Diversity and Pluralism

Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.

Article 8 – Non-Discrimination and Non-Stigmatization

In any decision or practice, no one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.

Article 9 – Autonomy and Individual Responsibility

Any decision or practice shall respect the autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others.

Article 10 – Informed Consent

- a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.
- b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.
- c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.

Article 11 – Privacy and Confidentiality

Any decision or practice shall be made or carried out with respect for the privacy of the persons concerned and the confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall not be used or disclosed for purposes other than those for which it was collected.

Article 12 – Solidarity and Cooperation

Any decision or practice shall pay due regard to solidarity among human beings and encourage international cooperation to that end.

Article 13 – Social Responsibility

Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the common good, including in the achievement of goals such as:

- (i) access to quality health care and essential medicines, including for reproductive health and the health of children;
- (ii) access to adequate nutrition and water;
- (iii) improvement of living conditions and the environment;
- (iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
- (v) reduction of poverty and illiteracy.

Article 14 – Sharing of Benefits

a) Benefits resulting from scientific research and its applications shall be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

- (i) special and sustainable assistance to the persons and groups that have taken part in the research;
- (ii) access to quality health care;
- (iii) provision of new diagnostics, facilities for new treatments or medical products stemming from the research;

- (iv) support for health services;
- (v) access to scientific and technological knowledge;
- (vi) capacity-building facilities for research purposes; and
- (vii) any other form consistent with the principles set out in this Declaration.

b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.

Article 15 – Responsibility towards the Biosphere

Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere.

CONDITIONS FOR IMPLEMENTATION

Article 16 – Decision-Making

Any decision or practice should:

- (i) be made or carried out following full and free discussion and in accordance with fair procedures;
- (ii) be made or carried out on the best available scientific evidence and methodology;
- (iii) pay due regard to any different information on the subject reasonably available to the decision-maker;
- (iv) be considered rigorously and based on the principles set out in this Declaration;
- (v) observe, when appropriate, proper procedures of risk assessment, management and prevention; and
- (vi) be considered individually, having regard to the circumstances of the persons, groups and communities concerned.

Article 17 – Honesty and Integrity

Any decision or practice should be made or carried out with:

- (i) professionalism, honesty and integrity;
- (ii) declaration of all conflicts of interest; and
- (iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.

Article 18 – Transparency

Any decision or practice should, subject to the provisions on privacy and confidentiality in Article 11:

- (i) be made or carried out transparently and openly;
- (ii) be available for appropriate scrutiny by the persons concerned and by civil society; and
- (iii) be susceptible to informed, wide and pluralistic public debate.

Article 19 – Periodic Review

Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with:

- (i) persons affected by any such decision or practice;
- (ii) members of relevant disciplines;
- (iii) appropriate bodies; and
- (iv) civil society.

Article 20 – Ethics Committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

- (i) assess the ethical, legal and social issues related to scientific research projects involving human beings;
- (ii) formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration, in accordance with the principles set out herein; and
- (iii) foster debate and education in bioethics.

Article 21 – Promoting Public Debate

States should promote opportunities for informed, pluralistic public debate, ensuring the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.

Article 22 – Risk Assessment, Management and Prevention

- a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.
- b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.

Article 23 – Transnational Practices

- a) States should take appropriate measures to ensure that any activity with bioethical implications, which is undertaken in whole or in part in different States, complies with the principles of this Declaration. Public and private institutions and professionals associated with a transnational activity should also take all appropriate measures to achieve the same end.
- b) When research is carried out in one country and funded partially or wholly by sources from one or more other countries, such research should be subjected to ethical review in all of the countries involved. This review should be based on ethical and legal standards, consistent with the principles set out in this Declaration, adopted by the States concerned.

IMPLEMENTATION AND PROMOTION OF THE DECLARATION

Article 24 – Role of States

- a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information. States should also take appropriate measures to involve young people in these activities.
- b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, in accordance with Article 20.
- c) States should establish processes for the assessment, management and prevention of risks. Such processes should include the identification of the issues, the characterization of risks and benefits, the development of options, the implementation of the decisions and the monitoring of the results.

Article 25 – Bioethics Education, Training and Information

- a) In order to implement and promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, States should endeavour to foster all forms of bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.
- b) States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 26 – International Cooperation

- a) States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
- b) Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.
- c) States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 27 – Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

- a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, in particular on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.

b) Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO.

Article 28 – Follow-up action by UNESCO

a) UNESCO shall take appropriate action to follow up this Declaration by evaluating new developments in science and technology and their applications according to the principles set out herein.

b) UNESCO shall reaffirm its commitment to dealing with the ethical aspects of the biosphere and, if necessary, shall endeavour to elaborate guidelines and international instruments, as appropriate, on ethical principles related to the environment and other living organisms.

c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall take appropriate measures to examine this Declaration in the light of scientific and technological development and, if necessary, to ensure its revision, in accordance with UNESCO's statutory procedures.

d) With respect to the principles set forth herein, this Declaration may be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

OPERATION OF THE PRINCIPLES AND DECLARATION

Article 29 – Interrelation and Complementarity of the Principles

In their interpretation and application, the principles set out in this Declaration are complementary and interrelated and each principle should be construed in the context of the other principles. Where there is conflict between the principles this should be resolved by balancing all those principles that are appropriate and relevant in the circumstances.

Article 30 – Restrictions on the Principles

No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law, and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

Article 31 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.