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*International Bioethics
Committee (IBC)*

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de bioéthique (CIB)*

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Elaboration of the Declaration on Universal Norms on Bioethics : Second Outline of a Text

This second version of an outline of a declaration on universal norms on bioethics has been elaborated by the Drafting Group for consideration by the International Bioethics Committee (IBC) at its Eleventh Session (Paris, 23-24 August 2004).

It was revised following a preliminary review by the IBC Drafting Group at its third meeting (Paris, 8-9 July 2004), taking into consideration the observations formulated during the information meeting of the Intergovernmental Bioethics Committee (IGBC) (Paris, 7 July 2004) and the third meeting of the UN Interagency Committee on Bioethics (Paris, 24-25 June 2004).

Declaration on Universal Norms on Bioethics

or

Universal Declaration on Bioethics and Humanity [Humankind / Human Beings]*

The General Conference,

Recalling 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 Universal Declaration of Human Rights of 10 December 1948, 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 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 the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

Also recalling 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 the other international and regional instruments, national legislation and regulations in the field of bioethics,

Also recalling the international and regional codes of conduct and guidelines and other ethical texts in the field of science and technology

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

* The words in [square brackets] offer variants of the wording concerned.

Considering also that it is the mission of UNESCO to develop universal principles and norms based on shared values to guide scientific and technological development and social transformation, in order to meet emerging challenges in science taking into account the responsibility of the present towards future generations,

Bearing in mind UNESCO's activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological development in a context of ethical reflection, and at promoting the sustainable use and conservation of biological diversity and the improvement of the relationship between human beings and their environment,

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

Recognizing that scientific and technological developments have been 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 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,

Bearing in mind that, without prejudice to the universal respect for, and observance of human rights and fundamental freedoms, cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, it is the common heritage of humanity,

Convinced that ethical reflection is an integral part of scientific and technological development and that bioethics plays today a predominant role in the social choices that need to be made,

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

Considering that questions of bioethics raised by advances in science and technology, which have been addressed in part by the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, should be treated as a whole, drawing on the principles already affirmed in these two international instruments and taking account not only of the current scientific context but also of future developments,

Proclaims the principles that follow and adopts the present Declaration.

[Use of Terms]

(Limited to scientific terms)

General Provisions

Scope

The principles set out in this Declaration:

- (i) apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, and
- (ii) apply to issues raised by scientific and technological developments and their applications, as well as their availability and access.

Aims

The aims of this Declaration are:

- to provide a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned;
- to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights law;
- to promote respect for biodiversity;
- to recognize the great benefit derived from scientific and technological developments, whilst ensuring that such development occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms, and to prevent practices contrary to human dignity;
- to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy makers and society as a whole;
- to promote the sharing and the greatest possible flow of knowledge concerning scientific and technological developments as well as the sharing of benefits, in particular with developing countries;
- to safeguard the interests of present and future generations.

General [Fundamental] Principles

Human Dignity, Human Rights and Justice

Bearing in mind that the principles set out in this Declaration derive [are drawn / flow] from the inherent dignity of the human person and the duty to promote universal respect for, and observance of human rights and fundamental freedoms, any decision or practice within the scope of this Declaration [to which this Declaration applies] shall be made or carried out in the respect of the inherent dignity of the human person, and in accordance with the universal principles of justice, human rights and fundamental freedoms.

Responsibility for [towards] the Biosphere

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall have due regard for the impact on the interconnections of all life forms and the special responsibility of human beings for the protection of life in its diversity and of the biosphere within which human beings exist.

Beneficence

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall optimize the positive benefits and reduce the possible harms of such decision or practice.

Cultural Diversity, Pluralism and Tolerance

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall take into account the various schools of thought, value systems, historical and cultural backgrounds, and philosophical and religious traditions that make up our societies. However, cultural diversity shall not be invoked to infringe upon the principles set out in this Declaration, nor to limit their scope.

Solidarity, Equity and Cooperation

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall be guided by the solidarity of humanity, in order to avoid discrimination and stigmatization of an individual, a family or a group, to ensure equity and to encourage the sharing of scientific knowledge and cooperation.

Implication of the [Fundamental] General Principles

Primacy of the human person

Non-discrimination and non stigmatization

Autonomy

Consent

Confidentiality and Right to Information

Benefit sharing

Specific Issues

Scientific research

Research involving human subjects

Healthcare

Human Reproduction and the Beginning of Life

Reproductive human cloning

End of Life

Palliative care

Tissue and Organ Transplantation

Genetic and other Personal Healthcare Data

Germ-line interventions

Sex Selection

Pharmacogenetics

Non-commercialization of the human body and its parts

Generic drugs

Right to healthy food

Right to a healthy environment

Procedures [Procedural Principles]

Provision on procedures which should be followed at national and international level in science and technology, in particular:

- the need for democratic and transparent procedures,
- rationality and agreement,
- intellectual honesty and integrity of research,
- principles governing the dissemination of scientific knowledge,
- dialogue between specialists, policy-makers and society,
- the promotion and establishment of national bioethics committees and review boards at appropriate levels,
- the need for public consultations,
- the regulation of transnational practices

Promotion and Implementation

Bioethics education, training and information

- a) In order to 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. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large.
- b) States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Solidarity and International Cooperation

- a) States should respect and promote solidarity towards individuals, families, populations and groups, with special regard for those rendered vulnerable by health or other personal, societal or environmental conditions and those with the most limited resources.
- b) States should foster the international dissemination of scientific information and make every effort to guarantee the free flow and sharing of scientific and technological knowledge [namely throughout the creation of research and education structures in the developing countries as well as the transfer of technology].

c) In the framework of international cooperation, States should promote cultural and scientific cooperation, endeavouring to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge and of the related know-how.

Role of States

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 sphere of education, training and public information.

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 therein. 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 will be addressed every two years to the International Bioethics Committee, which, after having examined them, will give its advice following the statutory procedures of UNESCO. After having examined the advice of IBC and the reports provided by States, the Intergovernmental Bioethics Committee will submit its opinion to the Director-General for transmission, together with the advice and recommendations of IBC, to the Member States, the Executive Board and the General Conference.

Follow-up action by UNESCO

a) UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of the life sciences and their applications through technologies, based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.

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

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

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

Nothing in this Declaration may be interpreted as implying for any States, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.