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*International Bioethics  
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de bioéthique (CIB)*

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## **Elaboration of the Declaration on Universal Norms on Bioethics : Third Outline of a Text**

**This third version of an outline of a declaration on universal norms on bioethics was elaborated by the Drafting Group of the International Bioethics Committee at its Fourth Meeting, held in Paris from 25 to 27 August 2004, immediately after the Eleventh Session of IBC (Paris, 23-24 August 2004).**

**This outline is not complete. It is not to be considered definite but as a step in the drafting process of the Drafting Group and the IBC in its entirety.**

# **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,

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\* 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.

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## [Use of Terms]

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(Limited to scientific terms)

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## General Provisions

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### Article 1 - 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.

## **Article 2 - 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.

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## **General [Fundamental] Principles**

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### **Article 3 - Human Dignity, Human Rights and Justice**

Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms and for the universal principle of justice.

### **Article 4 - Beneficence and Non-Maleficence**

Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice [to the persons concerned].

### **Article 5 - Respect for Cultural Diversity and Pluralism**

Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations. However, cultural diversity [such considerations] shall not be invoked to infringe upon the universal principles set out in this Declaration, nor to limit their scope.

### **Article 6 - Solidarity, Equity and Cooperation**

Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international cooperation [, in order *inter alia* to avoid discrimination and stigmatization of an individual, a family or a group].

### **Article 7 - Responsibility towards the Biosphere**

Any decision or practice within the scope of this Declaration shall have due regard for their impact on all forms of life and their interconnection and the special responsibility of human beings for the protection of biodiversity and the biosphere within which human beings exist.

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## **Derived Principles**

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### **Article 8 - Primacy of the Human Person**

Any decision or practice within the scope of this Declaration shall be founded on the recognition of the primacy of the human person, which shall prevail over the [sole] interest of science or society.

### **Article 9 - Non-Discrimination and non-Stigmatization**

In any decision or practice within the scope of this Declaration, no one shall be subjected to discrimination based on any grounds, including physical, mental or social conditions, diseases or genetic characteristics, nor shall such conditions or characteristics be used [invoked] to stigmatize an individual, a family or a group.

### **Article 10 - Autonomy and Responsibility**

Any decision or practice within the scope of this Declaration shall respect the autonomy of a person as an expression of his / her liberty to make decisions without prejudice to the autonomy of others.

### **Article 11 - [Informed] Consent**

- a) The prior, free, informed and express consent of the persons concerned shall be obtained in all medical or scientific research, treatment or diagnosis. Such consent may be withdrawn at any time.
- b) When, in accordance with domestic law consistent with international human rights law, a person is incapable of giving consent, such consent [authorization] should be obtained from his / her legal representative, having regard to the best interest of the person concerned.

### **Article 12 – Privacy and Confidentiality**

Any decision or practice within the scope of this Declaration shall be made or carried out with [full] respect for the privacy of the persons concerned and the confidentiality of their personal information. Such information cannot be used or disclosed for purposes other than those for which it was collected, except with the consent of the person concerned or in cases restrictively provided for by domestic law consistent with international human rights law.

### **Article 13 - Sharing of Benefits**

In accordance with international and domestic law, benefits resulting from scientific research and their applications should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:

- (i) special assistance to the persons and groups that have taken part in the research;
- (ii) access to medical care;
- (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;
- (iv) support for health services;
- (v) access to scientific and technological knowledge, in particular for developing countries;
- (vi) capacity-building facilities for research purposes;
- (vii) any other form consistent with the principles set out in this Declaration.

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## **Procedural Principles**

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### **Article 14 - Honesty and Integrity**

Any decision or practice within the scope of this Declaration shall:

- (i) be conducted with independence and intellectual honesty;
- (ii) respect the need for integrity in scientific and other research;
- (iii) avoid conflict of interest and duty; and
- (iv) pay 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 15 - Transparency and Openness**

Any decision or practice within the scope of this Declaration shall:

- (i) be made transparently and openly;
- (ii) be determined with particular regard to the circumstances known to the persons concerned;
- (iii) be subject to respect for privacy and confidentiality[, as stated in Article .....];
- (iv) be available for appropriate scrutiny by the persons concerned and by civil society; and
- (v) be susceptible to informed and pluralistic public debate, including in the media.

### **Article 16 - Scientific and Rational Methods**

Any decision or practice within the scope of this Declaration shall:

- (i) be made on the best available scientific information;
- (ii) pay due regard to any different information on the subject reasonably available to the decision-maker;

- (iii) be considered rigorously and in a principled manner;
- (iv) observe, when appropriate, proper procedures of risk assessment; and
- (v) be considered individually, allowing for the possibility of exceptions to general rules and practices.

#### **Article 17 - Community and Expert Consultation**

Any decision or practice within the scope of this Declaration, including those depending upon specialized scientific or other knowledge, shall take into account the need to reconsider regularly 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 18 - Fair Decision-Making Process**

Any decision or practice within the scope of this Declaration, where differences arise, shall be resolved following full and free discussion and in accordance with fair procedures.

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## **Procedures**

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#### **Article 19 - Risk Assessment**

When there is scientific evidence of threats of serious or irreversible damage to public health and human welfare or the environment [biosphere], provisional adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms.

#### **Article 20 - Ethics Committees**

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

- (i) to assess the ethical, legal and social issues related to scientific research projects and technological developments; and
- (ii) to devise guidelines and recommendations on issues within the scope of this Declaration, in accordance with the principles set out therein.

#### **Article 21 - Ensuring Public Debate**

States should ensure that citizens have an opportunity for informed, pluralistic public debate, ensuring the participation of all the stakeholders concerned and the relevant bioethics committee, and the expression of various socio-cultural, religious and philosophical opinions.

## **Article 22- Transnational Practices**

[International research should be subjected to ethical review in the country providing financial support for the activity as well as in the country where the research is to be carried out. This review should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.]

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### **[Specific Issues]**

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## **Promotion and Implementation**

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### **Article 23 - 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.

### **Article 24 - 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.

### **Article 25 - 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 sphere of education, training and public information.
- b) States should establish a framework for the assessment and management of risks. This framework 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 26- 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.

#### **Article 27 - 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.

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

#### **Article 28 - Interpretation**

In their interpretation and application the principles set out in this Declaration are interrelated and each principle should be construed in the context of the other principles.

#### **Article 29 - Restrictions**

No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by 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 30 - 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.