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

This fourth outline of a declaration on universal norms on bioethics was finalized by the Drafting Group of the International Bioethics Committee at its Sixth Meeting, held in Paris from 12 to 14 December 2004. On this occasion, the Drafting Group took account of the preliminary results of the written consultation on the third outline as well as comments formulated at the Fourth Meeting of the UN Inter-Agency Committee on Bioethics (Paris, 10 December 2004).

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 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),

Also recalling 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 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 that it is the mission of UNESCO to develop universal principles and norms 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 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,

Bearing in mind UNESCO's activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological developments in a context of ethical and societal 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, 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 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 field of study involving the theoretical and practical moral issues raised by medicine and the life sciences as applied to human beings and humanity’s relationship with the biosphere;
- (ii) the terms “bioethical issues” refer to the theoretical and practical moral issues raised by medicine and the life sciences as applied to human beings and humanity’s relationship with the biosphere as well as the availability and accessibility of scientific and technological developments and their applications;
- (iii) the terms “decision or practice” refer to a decision or practice arising within the scope of this Declaration involving bioethical issues.

Article 2- Scope

- a) The principles set out in this Declaration:
 - (i) apply, as appropriate, to individuals, families, groups, communities as well as to public and private institutions, corporations and States and humankind as a whole;
 - (ii) apply to bioethical issues;
 - (iii) apply to any related decision or practice.
- b) The principles set out in this Declaration apply to human beings, while recognizing that they have responsibilities towards other forms of life in the biosphere.

Article 3 - Aims

The aims of this Declaration are:

- (i) 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 individuals, groups and institutions concerned;
- (ii) to promote respect for human dignity and the protection 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 benefit 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, and to ensure that practices contrary to human dignity or peace will not be permitted;
- (iv) to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy makers, non governmental organizations, representatives of the civil society, all the persons concerned and society as a whole;
- (v) to promote the greatest possible flow and the sharing of knowledge concerning scientific and technological developments as well as the sharing of benefits, with particular attention to the needs and contributions of developing countries;
- (vi) to recognize the importance of respect for biodiversity;
- (vii) to safeguard and promote the interests of future generations.

Article 4 – Interrelation and Complementarity

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.

Article 5 - Restrictions

No restrictions shall be placed on the principles set out in this Declaration other than those consistent with international human rights law, prescribed by domestic 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.

General Principles

Article 6 - 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 7 – Equality, Justice and Equity

Any decision or practice shall respect the fundamental equality of all human beings and ensure that, whilst recognizing diversity among them, they are treated justly and equitably.

Article 8 - Beneficence and Non-Maleficence

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

Article 9 - 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 present in society. However, such considerations shall not be invoked to infringe upon the principles set out in this Declaration, nor to limit their scope.

Article 10 - Non-Discrimination and Non-Stigmatization

In any decision or practice, no one shall be subjected to discrimination based on any grounds, including gender, age, disability or other physical, mental or social conditions, diseases or genetic characteristics, and intended to infringe or having the effect of infringing human rights, fundamental freedoms or human dignity of an individual, nor shall such conditions or characteristics be used to stigmatize an individual, a family, a group or a community.

Article 11 - 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 12 - Informed Consent

- a) Any decision or practice in the field of scientific research shall not be made or carried out without the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn at any time and for any reason.
- b) Any decision or practice regarding the medical diagnosis and treatment of a person shall be made or carried out on the basis of:
 - (i) information appropriate to the decisions, provided to the person concerned;
 - (ii) the full participation of the person concerned;
 - (iii) the consent of the person concerned.
- c) When in accordance with domestic law a person does not have the capacity to consent, a research may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same medical condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

d) When in accordance with domestic law a person is incapable of giving informed consent, authorization for medical diagnosis and treatment should be obtained in accordance with domestic law in the best interest of the person concerned.

Article 13 – 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 cannot be used or disclosed for purposes other than those for which it was collected, except with the prior, free, informed and express consent of the person concerned.

Article 14 - Solidarity and Cooperation

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

Article 15 - Social Responsibility

Any decision or practice shall ensure, wherever possible, that progress in science and technology contributes in full equality to:

- (i) access to quality healthcare, including sexual and reproductive health;
- (ii) access to adequate nutrition and water;
- (iii) reduction of poverty and illiteracy;
- (iv) improvement of living conditions and the environment; and
- (v) elimination of the marginalization and the exclusion of persons on the basis of any ground, including gender, age or disability.

Article 16 - Sharing of Benefits

a) Benefits resulting from scientific research and its applications shall be shared with the society as a whole and the international community, in particular with developing countries. 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 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;
- (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 17 - Responsibility towards the Biosphere

Any decision or practice shall have regard for its 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.

Implementation Principles

Article 18 - Honesty and Integrity

Any decision or practice shall:

- (i) be made or carried out with professional independence and intellectual honesty;
- (ii) respect the need for integrity in scientific and other research;
- (iii) avoid conflict of interest; 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 19 - Transparency and Openness

Any decision or practice shall:

- (i) be made or carried out transparently and openly;
- (ii) be available for appropriate scrutiny by the persons concerned and by civil society;
- (iii) be susceptible to informed, wide and pluralistic public debate; and
- (iv) be subject in respect of all forgoing paragraphs to respect for privacy and confidentiality, as stated in Article 13.

Article 20 - Fair Decision-Making

Any decision or practice, where differences arise, shall be resolved following full and free discussion and in accordance with fair procedures and shall be determined with particular regard to the circumstances of the persons concerned;

Article 21 - Scientific and Rational Requirements

Any decision or practice shall:

- (i) be made or carried out on the best available scientific evidence;
- (ii) pay due regard to any different information on the subject reasonably available to the decision-maker;
- (iii) be considered rigorously and based on the principles set out in this Declaration;
- (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 22 - Periodic Review

Any decision or practice, 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.

Procedures

Article 23 - Risk Assessment

When scientific evidence of serious or irreversible damage to public health or human welfare or the environment is not sufficient, provisional, adequate and proportionate measures shall be taken in a timely manner. Such measures shall 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 to human rights and fundamental freedoms.

Article 24 - Ethics and Bioethics Committees

Independent, multidisciplinary and pluralist ethics or bioethics 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 herein.

Article 25 - Ensuring Public Debate

States should ensure that citizens have an opportunity for informed, pluralistic public debate, ensuring the participation of all the persons and bodies concerned, including relevant ethics or bioethics committees and non-governmental organizations, and the expression of various socio-cultural, religious and philosophical opinions.

Article 26 - Transnational Practices

a) States should take appropriate measures to ensure that any activity with bioethical implications, which is undertaken in whole or in part of different States, complies with the principles of this Declaration. No-State sponsors of and professionals associated with a transnational activity should also take all appropriate measures to achieve the same end.

b) Where a country provides financial support for research in another country, that research should be subjected to ethical review in both countries. 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.

Promotion and Implementation of the Declaration

Article 27 - 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, and 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 28 - Solidarity and International Cooperation

- a) States should foster 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].
- b) 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, the related know-how and the benefits thereof.
- c) States should respect and promote solidarity between and among individuals, families, groups and communities, with special regard for those rendered vulnerable by diseases or disabilities or other personal, societal or environmental conditions and those with the most limited resources.

Article 29 - 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 youth in these activities.
- b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics or bioethics committees, in accordance with Article 2a.
- c) States should establish processes for the assessment and management of risks. These 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 30 - 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, will be addressed every five years to the Director-General of UNESCO. The International Bioethics Committee 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 31 - 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 all 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 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 herein, this Declaration could be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

Article 32 - 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.