

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

INTRODUCTION

The Universal Declaration on the Human Genome and Human Rights, which was adopted unanimously and by acclamation by the General Conference of UNESCO at its 29th session on 11 November 1997, is the first universal instrument in the field of biology. The uncontested merit of this text resides in the balance it strikes between safeguarding respect for human rights and fundamental freedoms and the need to ensure freedom of research.

Together with the Declaration, UNESCO's General Conference adopted a resolution for its implementation, which commits States to taking appropriate measures to promote the principles set out in the Declaration and encourage their implementation.

The moral commitment entered into by States in adopting the Universal Declaration on the Human Genome and Human Rights is a starting point, the beginning of international awareness of the need for ethical issues to be addressed in science and technology. It is now up to States, through the measures they decide to adopt, to put the Declaration into practice and thus ensure its continued existence.

The General Conference,

Recalling that the Preamble of UNESCO's Constitution refers to "the democratic principles of the dignity, equality and mutual respect of men", rejects any "doctrine of the inequality of men and races", stipulates "that the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the dignity of men and constitute a sacred duty which all the nations must fulfil in a spirit of mutual assistance and concern", proclaims that "peace must be founded upon the intellectual and moral solidarity of mankind", and states that the Organization seeks to advance "through the educational and scientific and cultural relations of the peoples of the world, the objectives of international peace and of the common welfare of mankind for which the United Nations Organization was established and which its Charter proclaims",

Solemnly recalling its attachment to the universal principles of human rights, affirmed in particular in the Universal Declaration of Human Rights of 10 December 1948 and in the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, in the United Nations Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Declaration on the Rights of Mentally Retarded Persons of 20 December 1971, the United Nations Declaration on the Rights of Disabled Persons of 9 December 1975, the United Nations Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the United Nations Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power of 29 November 1985, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities of 20 December 1993, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction of 16 December 1971, the UNESCO Convention against Discrimination in Education of 14 December 1960, the UNESCO Declaration of the Principles of International Cultural Co-operation of 4 November 1966, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958 and the ILO Convention (N° 169) concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989,

Bearing in mind, and without prejudice to, the international instruments which could have a bearing on the applications of genetics in the field of intellectual property, inter alia the Bern Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO Universal Copyright Convention of 6 September 1952, as last revised in Paris on 24 July 1971, the Paris Convention for the Protection of Industrial Property of 20 March 1883, as last revised at Stockholm on 14 July 1967, the Budapest Treaty of the WIPO on International Recognition of the Deposit of Micro-Organisms for the Purposes of Patent Procedures of 28 April 1977, and the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1st January 1995,

Bearing in mind also the United Nations Convention on Biological Diversity of 5 June 1992 and emphasizing in that connection that the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question "the inherent dignity and (...) the equal and inalienable rights of all members of the human family", in accordance with the Preamble to the Universal Declaration of Human Rights,

Recalling 22 C/Resolution 13.1, 23 C/Resolution 13.1, 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3, 27 C/Resolution 5.15 and 28 C/Resolutions 0.12, 2.1 and 2.2, urging UNESCO to promote and develop ethical studies, and the actions arising out of them, on the consequences of scientific and technological progress in the fields of biology and genetics, within the framework of respect for human rights and fundamental freedoms,

Recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully

respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,
Proclaims the principles that follow and adopts the present Declaration.

A. HUMAN DIGNITY AND THE HUMAN GENOME

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

- (a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
- (b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 3

The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment including the individual's state of health, living conditions, nutrition and education.

Article 4

The human genome in its natural state shall not give rise to financial gains.

B. RIGHTS OF THE PERSONS CONCERNED

Article 5

- (a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.
- (b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.
- (c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.
- (d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.
- (e) If according to the law a person does not have the capacity to consent, research affecting his or her genome 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 genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 6

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

Article 7

Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.

Article 8

Every individual shall have the right, according to international and national law, to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome.

Article 9

In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

C. RESEARCH ON THE HUMAN GENOME

Article 10

No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at

national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

Article 12

(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

(b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

D. CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY

Article 13

The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Article 14

States should take appropriate measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration.

Article 15

States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.

Article 16

States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its application.

E. SOLIDARITY AND INTERNATIONAL CO-OPERATION

Article 17

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster, *inter alia*, research on the identification, prevention and treatment of genetically-based and genetically-influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

Article 18

States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

Article 19

(a) In the framework of international co-operation with developing countries, States should seek to encourage measures enabling:

(i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;

(ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;

(iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;

(iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

(b) Relevant international organizations should support and promote the initiatives taken by States for the above-mentioned purposes.

F. PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION

Article 20

States should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, *inter alia* through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular for those responsible for science policies.

Article 21

States should take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine,

and its applications. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.

G. IMPLEMENTATION OF THE DECLARATION

Article 22

States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.

Article 23

States should take appropriate measures to promote, through education, training and information dissemination, respect for the above-mentioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks among independent ethics committees, as they are established, to foster full collaboration.

Article 24

The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in this Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions.

Article 25

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 and fundamental freedoms, including the principles set out in this Declaration.

IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

The General Conference,

Considering the Universal Declaration on the Human Genome and Human Rights, which was adopted on this eleventh day of November 1997,

Noting that the considerations formulated by the Member States at the time of the adoption of the Universal Declaration are relevant for the follow-up of the Declaration,

1. *Urges* Member States:

- (a) in the light of the provisions of the Universal Declaration on the Human Genome and Human Rights, to take appropriate steps, including where necessary the introduction of legislation or regulations, to promote the principles set forth in the Declaration, and to promote their implementation;
- (b) to keep the Director-General regularly informed of all measures they have taken to implement the principles set forth in the Declaration;

2. *Invites* the Director-General:

- (a) to convene as soon as possible after the 29th session of the General Conference an *ad hoc* working group with balanced geographical representation, comprised of representatives of Member States, with a view to advising him on the constitution and the tasks of the International Bioethics Committee with respect to the Universal Declaration and on the conditions, including the breadth of consultations, under which it will ensure the follow-up to the said Declaration, and to report on this to the Executive Board at its 154th session;
- (b) to take the necessary steps to enable the International Bioethics Committee to ensure the dissemination and follow-up of the Declaration, and promotion of the principles set forth therein;
- (c) to prepare for the General Conference a global report on the situation world-wide in the fields relevant to the Declaration, on the basis of information supplied by the Member States and of other demonstrably trustworthy information gathered by whatever methods he may deem appropriate;
- (d) to take due account, in the preparation of his global report, of the work of the organizations and agencies of the United Nations system, of other intergovernmental organizations, and of the competent international non-governmental organizations;
- (e) to submit his global report to the General Conference, together with whatever general observations and recommendations may be deemed necessary in order to promote the implementation of the Declaration