



*The
Universal Declaration
on the Human Genome
and Human Rights:*

*from theory
to practice*

Preface

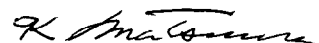
A reader discovering the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO at its 29th session (1997), will, I think, be struck by two things. First, by the scope of the text which, in a scientific and political context marked by such burning issues as manipulations of the human genome, human cloning and transgenesis, affirms or reaffirms intangible principles and values. And, second, by the many different actors concerned, due to several factors: the inherent nature of the subject which, like all ethical issues, lies at the interface of several disciplines; the universality of its approach, which should be informed by a public debate involving all components of society; the diversity of the economic, social and cultural contexts in which ethical thinking takes root throughout the world. For the thinking of each people develops in accordance with its own distinctive nature, as shaped by its history and traditions (legal, political, philosophical, religious, etc.).

In view of the new ethical issues raised by the sometimes astounding pace of progress in this field, the scope and potential reach of the Declaration made it necessary for UNESCO to devise a system for its follow-up and implementation – quite an innovation for an instrument that has no binding force.

On all sides the wish has been expressed that this system may rapidly become operational, so that the principles enshrined in the text can be translated into reality as soon as possible. The Declaration needs to be implemented as a matter of particular urgency in view of the ever quickening pace of technical and scientific progress in biology and genetics, where each advance almost unfailingly spawns new hopes for the improved well-being of humanity, together with unprecedented ethical dilemmas.

At its 30th session (1999), UNESCO's General Conference accordingly endorsed the 'Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights' drawn up by the International Bioethics Committee and approved by the Intergovernmental Bioethics Committee.

I am convinced that these Guidelines will serve to bolster the moral commitment entered into by Member States in adopting the Declaration, to give substance to the values it defends and to encourage the greatest possible number to address ethical concerns, rekindled every day by new questions to which there are no clear-cut answers and whose outcome may now affect the destiny that humanity is forging for itself.



Koïchiro Matsuura

*Universal Declaration on the Human Genome and Human Rights**

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

** Adopted unanimously and by acclamation on 11 November 1997 by the 29th session of the General Conference of UNESCO.*

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.

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.

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 applications.

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 abovementioned purposes.

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.

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 abovementioned 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
(30 C/Resolution 23)**

The General Conference,

Recalling the Universal Declaration on the Human Genome and Human Rights,

Bearing in mind 29 C/Resolution 17 entitled 'Implementation of the Universal Declaration on the Human Genome and Human Rights',

Noting resolution 1999/63 entitled 'Human Rights and Bioethics', adopted by the United Nations Commission on Human Rights at its fifty-fifth session,

Also noting the Director-General's report on the implementation of the Declaration (30 C/26 and Add.),

1. *Endorses* the Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights annexed to this resolution;
2. *Invites* the Director-General to transmit them to the Secretary-General of the United Nations, with a view to the fifty-fourth session of the General Assembly of the United Nations and to the work of the relevant bodies, in particular the United Nations Commission on Human Rights;
3. *Further invites* the Director-General to transmit them to the United Nations Specialized Agencies and to other relevant international governmental and non-governmental organizations and to disseminate them as widely as possible;
4. *Invites* Member States, international governmental and non-governmental organizations and all identified partners to take all the necessary steps to implement the Guidelines.

** Resolution adopted by the General Conference of UNESCO at its 30th Session, on 16 November 1999.*

Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights

1. WHY GUIDELINES?

The Universal Declaration on the Human Genome and Human Rights sets forth the basic principles bearing on research in genetics and biology and the application of its results. In order to guarantee the application of these principles, the Declaration recommends that they be made known, disseminated and given shape as measures, especially in the form of legislation or regulations. The Declaration also specifies the measures that Member States should take for its application.

The implementation of the Declaration is all the more urgent since scientific progress in genetics and biology is accelerating and both giving humankind hope and creating ethical dilemmas.

These Guidelines seek to identify not only the tasks devolving on the different actors in the implementation of the Declaration but also modalities of action for their achievement.

2. WHAT TO DO?	3. HOW?	4. FOR WHOM ARE THESE GUIDELINES INTENDED?
<p>2.1 The dissemination of the principles set forth in the Universal Declaration on the Human Genome and Human Rights is a priority and a preliminary condition for their effective application. Thus, this dissemination must be as wide as possible and especially oriented towards scientific and intellectual circles, people involved in education and training, especially in universities, and decision-making bodies such as parliaments.</p> <p>2.2 Consciousness-raising, education, and training regarding the principles contained in the Declaration are especially important goals if each and every member of society is to grasp the ethical issues at stake in genetics and biology.</p>	<p>3.1.1 The translation of the Declaration into the largest possible number of national languages.</p> <p>3.1.2 The organization of seminars, symposia and conferences at the international, regional, subregional and national levels (in Benin, Croatia, Monaco, United Republic of Tanzania, Uruguay, etc.).</p> <p>3.2.1 The drafting of the simplest and most explicit possible commentary on each of the articles of the Declaration.</p> <p>3.2.2 The publishing of books on the subject, designed both for a non-specialist public and for the various professional groups concerned (for example scientists, philosophers, jurists, judges and journalists).</p>	<p>Experience shows that to implement an international instrument, synergy needs to be created between all actors at the different levels. Today, inter-national action is characterized by partnership in which each actor, while retaining his identity and specific nature, complements the role played by the others.</p> <p>These guidelines are intended for:</p> <ul style="list-style-type: none">• States and National Commissions for UNESCO;• UNESCO (Headquarters and field offices);• the International Bioethics Committee (IBC);

2.3 Exchanges of studies and analyses pertaining to questions of bioethics, and programmes of information on this subject must be organized at the international and regional levels, especially in order to identify practices that could be contrary to human dignity.

2.4 The establishment of a dynamic relationship between the different actors is desirable in order to promote dialogue among industrialists, members of civil society, vulnerable groups, scientists and political leaders.

3.2.3 The preparation of programmes of education and training in bioethics designed for the secondary and university levels.

3.2.4 The preparation of training programmes in bioethics designed for teachers and trainers.

3.2.5 The preparation of information kits on specific subjects and their dissemination among public and private decision-makers and the media.

3.2.6 The production of audiovisual materials on bioethics for the general public.

3.2.7 Multimedia exhibitions designed especially for young people.

3.3.1 The creation of bodies such as independent, pluralist and multidisciplinary ethics committees which would be special partners for decision-makers, the scientific community and civil society.

3.3.2 The networking of these institutions so as to facilitate communication and exchanges of experience among them, especially for carrying out joint activities.

3.4.1 The involvement of the economic actors, especially from industry, and of social organizations such as associations of vulnerable persons and their families and friends.

3.4.2 The organization of public debates on issues covered by the Declaration and the exploration of various approaches (conferences for consensus-building, public consultation, etc.).

- the Intergovernmental Bioethics Committee (IGBC);
- bodies and specialized institutions of the United Nations system;
- competent governmental and non-governmental organizations at the international, regional and national levels;
- public and private decision-makers, especially in science policy;
- lawmakers;
- ethics committees and similar bodies;
- scientists and research workers;
- individuals, families and populations with genetic mutations that may lead to illnesses or disabilities.

- 2.5 Freedom of research, especially in genetics and biology, should be respected and scientific and cultural co-operation encouraged and broadened, especially between the countries of the North and the South.
- 2.6 Examples of legislation and regulations that embody the principles set out in the Declaration should be prepared as a source of inspiration for States.
- 2.7 As most of the issues covered by the Declaration are at the interface of the fields which fall within the assigned tasks of the various organizations, it is through effective co-operation that they will be able to deal with issues in a concerted manner.*

- 3.5.1 In-depth analysis of the conditions which encourage freedom of research and those which hamper it.
- 3.5.2 The periodic examination by the IBC of co-operation between the countries of the North and the South and an examination of any obstacles, in order to overcome them.
- 3.6.1 The organization by the IBC of international and/or regional workshops aimed at providing a standard framework of legislation and regulations in the field of bioethics.
- 3.6.2 The collection and processing of information on the international and regional instruments pertaining to bioethics as well as on national legislation and/or regulations.
- 3.7.1 The setting up of an inter-agency committee within the United Nations system open to other interested inter-governmental organizations and responsible for the co-ordination of activities related to bioethics.

** See paragraph 3 of resolution 1999/63 entitled "Human Rights and Bioethics", adopted by the United Nations Commission on Human Rights at its Fifty-fifth Session.*

5. EVALUATION

Five years after the adoption of the Declaration, in 2002, UNESCO should evaluate both the results obtained through the guidelines defined above and the impact of the Universal Declaration on the Human Genome and Human Rights worldwide (States, intellectual communities, institutions of the United Nations system, intergovernmental organizations - international and regional - competent non-governmental organizations, etc.).

The evaluation, which should be carried out in accordance with the procedures established by the Executive Board and the General Conference, in particular because of its budgetary implications, will be examined at a joint session of IBC and IGBC and will be submitted by the Director-General in 2003 to the statutory bodies of the Organization along with any relevant recommendations.