

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



# Preface

The Universal Declaration on the Human Genome and Human Rights marks an important stage in the international community's growing awareness that scientific and technological progress raises important ethical issues and has important human and social implications.

The undisputed merit of this first universal instrument in the field of biology resides in the fact that it strikes a balance between guaranteeing respect for human rights and fundamental freedoms and the need to protect freedom of research.

This work sets out to retrace the various stages in the conception, development and formulation of the successive versions of this instrument which, while responding to the expectations of States, incorporated the findings of the consultation carried out among scientists, philosophers, lawyers, international intergovernmental and non-governmental organizations and associations representative of society in all its diversity.

It is now the responsibility of States to breathe life into the Declaration, *inter alia*, by reflecting it in their domestic legislation. Eventually, UNESCO should perhaps, on the basis of a searching evaluation of the measures taken and the prevailing situation, take the initiative once again so as to entrench the principles enshrined in the Declaration more firmly in law.

A handwritten signature in black ink, consisting of a tall, thin vertical stroke on the left, followed by a series of connected, wavy horizontal strokes that end in a small upward hook.

Federico Mayor,  
Director-General of UNESCO

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## **ABBREVIATIONS AND ACRONYMS**

CCNE	National Consultative Ethics Committee for Health and Life Sciences of France
CDBI	Steering Committee on Bioethics of the Council of Europe
CIOMS	Council for International Organizations of Medical Sciences
CR	Committee on Conventions and Recommendations of the Executive Board of UNESCO
DNA	Deoxyribonucleic acid
ECOSOC	Economic and Social Council
FAO	Food and Agriculture Organization
FISP	International Federation of Philosophical Societies
GMO	Genetically Modified Organism
HUGO	Human Genome Organization
IALS	International Association of Legal Science
IBC	International Bioethics Committee of UNESCO
ICJ	International Court of Justice
ICPHS	International Council for Philosophy and Humanistic Studies
ICSU	International Council for Science
ILO	International Labour Organization
ISSC	International Social Science Council
OAS	Organization of American States
OAU	Organization of African Unity
TRIPs	Trade Related Aspects of Intellectual Property Rights Agreement
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WFSW	World Federation of Scientific Workers
WMA	World Medical Association
WTO	World Trade Organization

## **LIST OF INTERNATIONAL INSTRUMENTS AND DOCUMENTS CITED**

### ***Council for International Organizations of Medical Sciences (CIOMS)***

Declaration of Manila. 16 September 1981.

Declaration of Inuyama City. Japon, July 1990.

Declaration of Ixtapa. Mexique, 1994.

International Ethical Guidelines for Biomedical Research Involving Human Subjects, 1993.

### ***International Council for Science (ICSU)***

Declaration on Gene Patenting, 1992.

### ***International Labour Organization (ILO)***

Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation. 25 June 1958 (entry into force on 15 June 1960).

Convention (N°169) concerning Indigenous and Tribal Peoples in Independent Countries. 27 June 1989 (entry into force on 5 September 1991).

### ***United Nations (UN)***

Charter of the United Nations. San Francisco, 26 June 1945 (entry into force on 24 October 1945).

Convention on the Prevention and Punishment of the Crime of Genocide. 9 December 1948 (entry into force on 12 January 1951).

Convention on the Elimination of All Forms of Racial Discrimination. 21 December 1965 (entry into force on 4 January 1969).

International Covenant on Civil and Political Rights. 16 December 1966 (entry into force on 23 March 1976).

International Covenant on Economic, Social and Cultural Rights. 16 December 1966 (entry into force on 3 January 1976).

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. 16 December 1971 (entry into force on 26 March 1975).

Convention on the Elimination of All Forms of Discrimination Against Women. 18 December 1979 (entry into force on 3 September 1981).

Agreement Governing the Activities of States on the Moon and other Celestial Bodies. 18 December 1979 (entry into force on 11 July 1984).

Convention on the Law of the Sea. Montego Bay, 10 December 1982 (entry into force on 16 November 1994).

Convention on the Rights of the Child. 20 November 1989 (entry into force on 2 September 1990).

Convention on Biological Diversity. 5 June 1992 (entry into force on 29 December 1993).

Standard Rules on the Equalization of Opportunities for Persons with Disabilities. 20 December 1993.

Universal Declaration of Human Rights. Paris, 10 December 1948.

Declaration on the Principles of International Law concerning Friendly Relations and Co-operation among States in accordance with the Charter of the United Nations (2625 (XXV)). 24 October 1970.

Declaration on the Rights of Mentally Retarded Persons. 20 December 1971.

Declaration on the Rights of Disabled Persons. 9 December 1975.

Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power. 29 November 1985.

Declaration on the Right to Development. 4 December 1986.

Resolution 728 F (XXVIII) adopted by the Economic and Social Council of the United Nations on 30 July 1959, giving the Commission on Human Rights certain responsibilities with regard to the treatment of communications dealing with human rights.

Resolution 1235 (XLII) adopted by the Economic and Social Council of the United Nations on 6 June 1967, authorizing the Commission on Human Rights and the Sub-Commission on Prevention of Discrimination and Protection of Minorities to examine information relevant to gross violations of human rights and fundamental freedoms.

Resolution 1503 (XLVIII) 'Procedure for dealing with communications relating to violations of human rights and fundamental freedoms' adopted by the Economic and Social Council of the United Nations on 27 May 1970.

Resolution 1985/17 adopted by the Economic and Social Council of the United Nations on 28 May 1985, and establishing the United Nations Committee on Economic, Social and Cultural Rights.

Resolution 1993/91 'Human Rights and Bioethics' adopted by the United Nations Commission on Human Rights on 10 March 1993.

Resolution 1997/71 'Human Rights and Bioethics' adopted by the United Nations Commission on Human Rights on 16 April 1997.

Resolution A/RES/53/152 'The Human Genome and Human Rights' adopted by the General Assembly of the United Nations on 9 December 1998.

### ***United Nations Educational, Scientific and Cultural Organization (UNESCO)***

Constitution of UNESCO. London, 16 November 1945.

Convention for the Protection of Cultural Property in the Event of Armed Conflict. The Hague, 14 May 1954 (entry into force on 7 August 1956).

Convention against Discrimination in Education. Paris, 14 December 1960 (entry into force on 22 May 1962).



- Universal Copyright Convention as revised at Paris on 24 July 1971 (entry into force on 10 July 1974).
- Convention for the Protection of the World Cultural and Natural Heritage. Paris, 16 November 1972 (entry into force on 17 December 1975).
- Regional Convention on the Recognition of Studies, Diplomas and Degrees in Higher Education in Latin America and the Caribbean. Mexico City, 19 July 1974 (entry into force on 14 June 1975).
- Convention on the Recognition of Studies, Diplomas and Degrees in Higher Education in the Arab States. Paris, 22 December 1978 (entry into force on 7 August 1981).
- Convention on the Recognition of Studies, Diplomas and Degrees concerning Higher Education in the States belonging to the Europe Region. Paris, 21 December 1979 (entry into force on 19 February 1982).
- Regional Convention on the Recognition of Studies, Certificates, Diplomas, Degrees and other Academic Qualifications in Higher Education in the African States. Arusha, Tanzania, 5 December 1981 (entry into force on 1 January 1983).
- Regional Convention on the Recognition of Studies, Diplomas and Degrees in Higher Education in Asia and the Pacific. Bangkok, 16 December 1983 (entry into force on 23 October 1985).
- Declaration of the Principles of International Cultural Co-operation. 4 November 1966.
- Declaration on Race and Racial Prejudice. 27 November 1978.
- Universal Declaration on the Human Genome and Human Rights. 11 November 1997.
- Recommendation concerning the Status of Teachers. Paris, 5 October 1966.
- Recommendation concerning Education for International Understanding, Co-operation and Peace and Education relating to Human Rights and Fundamental Freedoms. Paris, 19 November 1974.
- Revised Recommendation concerning Technical and Vocational Education. Paris, 19 November 1974.
- Recommendation on the Status of Scientific Researchers. Paris, 20 November 1974.
- Resolution 15 C/12.2 'Amendment to Rule 32 of the Rules of Procedure (Functions of the Legal Committee)', 16 November 1968.
- Resolution 20 C/3/1.1/3 'Respect for human rights', 27 November 1978.
- Resolution 21 C/3/03 'Plan for the development of human rights teaching', 24 October 1980.
- Resolution 22 C/13.1 'Major Programme XIII: Peace, international understanding, human rights and the rights of peoples', 25 November 1983.
- Resolution 23 C/13.1 'Major Programme XIII: Peace, international understanding, human rights and the rights of peoples', 8 November 1985.
- Resolution 23 C/13.3 'System of reporting on the steps taken by Member States to apply the Recommendation concerning education for international understanding, co-operation and peace and education relating to human rights and fundamental freedoms', 8 November 1985.
- Resolution 24 C/13.1 'Major Programme XIII: Peace, international understanding, human rights and the rights of peoples', 19 November 1987.
- Resolution 25 C/5.2 'Philosophy, ethics and the life sciences', 15 November 1989.
- Resolution 25 C/7.3 'Human rights and scientific and technological progress', 15 November 1989.
- Resolution 27 C/5.15 'Preparation of an international instrument for the protection of the human genome', 15 November 1993.
- Resolution 28 C/0.12 'Medium-Term Strategy for 1996-2001', 13 November 1995.
- Resolution 28 C/2.1 'Major Programme II: the sciences in the service of development', 14 November 1995.

Resolution 28 C/2.2 'Drawing up of an international declaration on the human genome and the protection of human rights', 14 November 1995.

Resolution 29 C/17 'Implementation of the Universal Declaration on the Human Genome and Human Rights', 11 November 1997.

Declarations of Valencia relative to the Human Genome Project (1988) and concerning Ethics and the Human Genome Project (1990), from work done in workshops on international co-operation relative to the Human Genome Project, organized by UNESCO.

Declaration of Moscow, 1991, adopted at the 'International Meeting on Bioethics and the Social Consequences of Biomedical Research' organized by UNESCO.

Declaration of Caxambu, 1992, adopted at the North-South Meeting on the human genome organized by UNESCO.

### ***World Intellectual Property Organization (WIPO)***

Bern Convention for the Protection of Literary and Artistic Works. 9 September 1886, as last revised in Paris on 24 July 1971.

Paris Convention for the Protection of Industrial Property. 20 March 1883, as last revised at Stockholm on 14 July 1967.

Budapest Treaty on International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures. 28 April 1977

### ***World Medical Association (WMA)***

Code of Nuremberg, 1947.

Declaration of Helsinki, June 1964 (revised in October 1975 in Tokyo, in October 1983 in Venice).

### ***World Trade Organization (WTO)***

Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization (WTO), entered into force on 1st January 1995.

## **Regional level**

### ***Africa***

African Charter on Human and Peoples' Rights. Nairobi, 28 June 1981 (entry into force on 21 October 1986).

Resolution AHG/Res. 254 (XXXII) on Bioethics. Yaoundé, July 1996.

### ***America***

American Declaration of the Rights and Duties of Man. December 1791.

American Convention on Human Rights. San José, Costa Rica, 22 November 1969 (entry into force on 18 July 1978).

***Council of Europe***

European Convention for the Protection of Human Rights and Fundamental Freedoms. 4 November 1950 (entry into force on 3 September 1953).

Draft Outline-Convention on Bioethics, 1994.

Recommendation N° R(90)3 of the Committee of Ministers to Member States concerning Medical Research on Human Beings. 6 February 1990.

Recommendation N° R(92)3 of the Committee of Ministers to Member States on Genetic Testing and Screening for Health Care Purposes. 10 February 1992.

## INTRODUCTION

In 1993, Mr Federico Mayor, Director-General of UNESCO had the foresight and vision to set up the International Bioethics Committee (IBC) so that the Organization could play its full role in the world of the future. His goal for the Committee was that it should conduct a world-wide debate on the ethical, social and human consequences of the development of the life sciences. The IBC, the only international body working in the field of bioethics, consisted of about fifty leading figures, appointed in their personal capacity, from every region of the world. The IBC's transdisciplinary composition meant that it was able to comprehend the diversity of the issues raised by the progress of research and applications in the life sciences.

At its 27th session, by its Resolution 27 C/5.15 (15 November 1993), the General Conference of UNESCO approved the creation of the IBC. By the same Resolution, the General Conference asked the Director-General to prepare an international instrument for the protection of the human genome.

The Director-General thus entrusted the IBC with the vital task of exploring the conditions for the preparation of an international instrument for the protection of the human genome. The IBC Legal Commission, of which I was the Chairman, was given the task of making all relevant proposals on both the form and the substance of the proposed international instrument. A first outline, examined by the IBC at its second session, led to the preparation of an Outline of the declaration (7 March 1995) based on universally acknowledged rights and freedoms.

After examining a Report on this subject, the General Conference at its 28th session asked the Director-General, in Resolution 28 C/2.2 (14 November 1995), to draw up a preliminary draft declaration and, in accordance with established practice in the United Nations system, to convene a committee of governmental experts to finalize this declaration.

In accordance with this Resolution and in the light of Decision 150 EX/8.3 of the Executive Board at its 150th session (14-31 October 1996), the Director-General asked the Member States to appoint representatives to the committee of governmental experts for the finalization of a declaration on this subject. This Committee, of which I was also the Chairman, met at UNESCO Headquarters from 22 to 25 July 1997. Based on the deliberations and work of the International Bioethics Committee of UNESCO between 1993 and 1997, this Committee of Governmental Experts drafted the text of the *Draft of a Universal Declaration on the Human Genome and Human Rights* (25 July 1997) which was adopted by consensus. This Draft Declaration was presented to the General Conference at its 29th session.

The 29th Session of the General Conference adopted the *Universal Declaration on the Human Genome and Human Rights*, unanimously and by acclamation, on 11 November 1997. By Resolution 29 C/17 entitled 'Implementation of the Universal Declaration on the Human Genome and Human Rights', the General Conference laid the foundations of the modalities for the follow-up of the implementation of the Declaration.

Aware of the significance and scope of this Declaration, the United Nations General Assembly during its 53rd session, at the 50th anniversary of the Universal Declaration of Human Rights, adopted Resolution A/RES/53/152 by consensus on 9 December 1998. By this Resolution, entitled 'The Human Genome and Human Rights', the General Assembly 'endorses the Universal Declaration on the Human Genome and Human Rights adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organization'.

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

The present work sets forth the main stages in the preparation of this Declaration which went through nine successive versions. To my knowledge, this is the first work to trace the history and genesis of an international instrument. Not only will this work be very useful for the jurist and the historian but the various stages through which the Declaration went during its preparation provide invaluable pointers towards understanding it.

This Declaration was the result of a joint effort. Every member of the International Bioethics Committee of UNESCO took part in the drafting of one article or another and most of the Member States of UNESCO contributed to it.

This remarkable task, carried out under the competent and vigorous leadership of Ms Noëlle Lenoir, then Chairperson of the International Bioethics Committee of UNESCO, was accomplished with serenity as well as a sense of urgency. The project was perfectly attuned to the political will of the Member States, expressed in the resolutions of the General Conference, which felt that the time had come for the international community to adopt an international instrument bearing especially on the human genome.

This Declaration is aimed at ensuring freedom of research in genetics and its applications, in keeping with respect for fundamental rights and liberties. In this legal document, the concept of the human genome refers to all the genes of each individual - in their twofold aspect of genetic material (DNA molecules) and genetic information - as well as to all the genes that constitute the human species. The term 'Universal' used to qualify this Declaration is designed to emphasize the exceptional scope of this document.

The Declaration has a preamble and twenty-five articles. These articles are assembled in logical order under seven sections.

The Preamble recalls that the aims and principles of the Declaration are in line with UNESCO's ideals and the ethical mission entrusted to it by its Constitution. In human genetics, this mission is of vital importance in view of the risks faced by humanity. These risks, which encompass the risk of a collapse of society's material and moral solidarity towards vulnerable persons and the risk of an increase in the inequality of distribution of the benefits of research and its applications, could jeopardize the principle of the equal dignity of individuals.

The preamble also makes reference to the various international instruments, adopted by the United Nations in the field of human rights, that underpin the Declaration. Among these instruments, the Universal Declaration of Human Rights of 10 December 1948 has a special place because it enshrines the universal recognition of human rights and forms the matrix of the international law of human rights.

### **A. *Human Dignity and the Human Genome***

By affirming the fundamental unity of the human species in Article 1, the Declaration underlines the supreme value attached to the preservation of this unity. This affirmation is based on the dignity of all human beings at the same time as it recognizes their diversity. In doing so, it is in line with the Declaration on Race and Racial Prejudice adopted by UNESCO on 27 November 1978 which proclaims in Article 1: 'All human beings belong to a single species and are descended from a common stock. They are born equal in dignity and rights and all form an integral part of humanity'.

Article 1 of the Universal Declaration on the Human Genome and Human Rights also asserts that, in a symbolic sense, the human genome is the heritage of humanity. The idea here is to underline the fact that research on the human genome and the applications that flow therefrom entail the responsibility of humanity as a whole, in the interest of present and future generations. Indeed, this research may affect both individuals and the human species. This responsibility of the international community is a major ethical imperative. It is in this sense that the concept of the heritage of humanity must be understood.

It is important to recall that UNESCO has frequently made reference to this concept which is cited especially in its Constitution and in different international conventions. Thus, for example, the Declaration of the Principles of International Cultural Co-operation of 4 November 1966 states in Article 1, paragraph 3, that: 'all cultures form part of the common heritage belonging to all mankind. In this context, the affirmation had symbolic value, expressing the emergence of awareness, in the world community, of the need to safeguard a common cultural heritage in its various constituent elements'<sup>(1)</sup>.

Article 2 of the Declaration asserts that the genetic characteristics of the person can in no way justify limits on the recognition of his or her dignity or the exercise of his or her rights. This is a fundamental principle whose corollary is the prohibition of all discrimination based on genetic characteristics as set forth in Article 6. This article is derived from Article 2 of the Universal Declaration of Human Rights of 10 December 1948 ('Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status'), and adds the genetic criterion to it.

Many other instruments adopted by UNESCO also refer to this principle of non-discrimination, especially the Convention against Discrimination in Education adopted by UNESCO on 14 December 1960 and the Declaration on Race and Racial Prejudice already referred to. In taking the dignity of the human person as its reference, the Declaration seeks above all to condemn any attempt to draw political or social inferences from a purported distinction between 'good' genes and 'bad' genes.

By this article, the Declaration also rejects all genetic reductionism. Indeed, there is a risk that knowledge about the human genome, which is a fundamental form of knowledge, might be interpreted in a manner that is contrary to the dignity of the individual as a free and responsible being. As of now, there are already theories attempting to demonstrate the view that certain character or behavioural traits can be attributed to genetic factors alone. By explicitly condemning genetic reductionism, the Declaration seeks to highlight the danger of these theories which clearly have underlying eugenic designs.

Similarly, Article 3 of the Declaration rejects all forms of genetic determinism that might lead to the idea that the individual is genetically 'programmed' from the very beginning of his life. Genetic determinism of this kind is ignorant of the complexity of the interactions that exist between the human genome and its environment taken in the broad sense of the term. By underlining the influence of living conditions, namely the environment in its natural as well as social aspects, on the development of the genetic potentialities of individuals, this article reinforces the affirmation that a human being cannot be reduced to his genetic characteristics alone.

Article 4 emphasizes the inalienability of the human body and especially prohibits the commercialization of human genes and gene sequences. On the subject of patentability, this article specifically rules out the patenting of a gene or gene sequence 'in its natural state'. However, this article does not exclude the possibility that the results of gene research might be the object of intellectual property rights in accordance with Article 27, paragraph (b), of the Universal Declaration of Human Rights of 10 December 1948. Consequently, the legal protection of the results of research has not been eliminated. Moreover, the lack of appropriate financing is detrimental to the dynamism of such research which requires considerable investment. The legal protection of inventions must take account of the ethical imperatives that might justify certain restrictions on research.

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1. The concept of common heritage has also been applied in the field of values by the Council of Europe: the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 thus refers in its Preamble to the 'common heritage of political traditions, ideals, freedom and the rule of law' that bring together, in this case, the European States.

## **B. Rights of the Persons Concerned**

The principles of the protection of an individual from the consequences of research on the human genome are based on a set of rights that flow directly from the principles affirmed by the Universal Declaration of Human Rights of 10 December 1948.

In the various articles of this section, the words 'research', 'treatment' and 'diagnosis' refer to any action, with a medical or scientific goal, that is performed on the genome of an individual and is likely to have physical, psychological, economic, social or other consequences on the individual concerned or on the group to which he or she belongs.

The different paragraphs of Article 5 are aimed at protecting the rights of the persons concerned and underline the need to prevent all practices contrary to dignity, freedom and human rights. This article as a whole sets forth the essential principles to which any intervention affecting the human genome must be subordinated, namely: firstly, the principle of precaution which is a corollary of the right to security and health and, secondly, the principle of prior, free and informed consent which is a consequence of the right to individual freedom.

The struggle against discrimination on any grounds (see especially Article 2 of the Universal Declaration of Human Rights) and in any field (employment, health and education) whatsoever is an important part of the international law of human rights. Many international instruments have been devoted to the principle of non-discrimination, which is a corollary of the principle of equality and of respect for dignity. These instruments consider the struggle against discrimination from two standpoints: their nature (race or sex discrimination in particular<sup>(2)</sup>) and their field of application to a specific right (for example the right to work, the right to the protection of health and the right to education<sup>(3)</sup>).

Article 6 of the Declaration extends and complements these instruments by prohibiting all discrimination based on genetic characteristics. What it does is to prohibit discrimination against an individual or against groups, especially ethnic minorities with certain specific genetic characteristics, in the exercise of their rights, for example in access to employment or social protection. In order to maintain the possibility of 'positive' discrimination, the Declaration specifies that the forms of discrimination proscribed are those that infringe human rights, fundamental freedoms and dignity. Particular genetic characteristics could therefore, as the case may be, justify differences of treatment provided that these differences of treatment correspond to a purpose of general interest and are in keeping with the principle of proportionality.

Article 7 guarantees the protection of the confidentiality of genetic data associated with an identifiable person. In this respect, the Declaration is related to the general principle of respect for privacy, affirmed especially in Article 12 of the Universal Declaration of Human Rights and Article 17 of the International Covenant on Civil and Political Rights<sup>(4)</sup>. This protection would appear to be indispensable given the specific risks created by access to this information. Genetic data is of a kind hitherto quite unknown since it provides information not only on the individual but also on his or her relatives and descendants. With the current scientific uncertainty about the nature and importance of the role played by genes and the possibility of misuse, emphasis is being placed on the ethical principle of confidentiality. This is why this article lays down that confidentiality must be protected under the conditions laid down by law, especially with regard to relationships between individuals and insurance companies or employers.

To reinforce the protection of the person in the event of intervention on his or her genome, Article 8 stipulates the right to just reparation for damage. Indeed, the law is increasingly tending to recognize the right to just reparation for victims of unjustified damage resulting from medical

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2. Cf. the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978 and the Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979.

3. Cf. the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, and the UNESCO Convention against Discrimination in Education of 14 December 1960.

4. Cf. also the American Convention on Human Rights dated 22 November 1969 (Art. 11-2) and the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 (Art. 8-1).

intervention, and goes so far as to accept the notion of liability for risks (and no longer for mistakes alone). Furthermore, this right may be invoked only if an intervention affecting a person's genome proves to be determining with respect to the damage that he or she claims to have sustained. The term 'just' seeks to take account of the specific circumstances in which the damage has occurred. Finally, in order to rule out any proceedings for liability on the part of an individual's descendants, the article indicates that no individual may claim to have sustained damage unless it has been directly caused by an intervention affecting his or her genome.

While the obtaining of an individual's prior, free and informed consent is standard practice in research, treatment and diagnosis pertaining to his or her genome, it is clear that certain situations may justify exceptions to this principle. Indeed, in civil cases, a judge in a particular country may decide to have recourse to genetic testing in a paternity-search procedure. In criminal cases, the genetic fingerprinting of an accused individual may be ordered by a judge. Article 9 specifies that these exceptions may be made only by law and for compelling reasons, and that they must be made within the bounds of public international law and the international law of human rights. There can be no question of opening the way to interpretations justifying acts contrary to international laws on human rights and the Constitution of UNESCO.

With a view to ensuring strict protection, the Declaration does not allow any possibility of making a general exception to the principle of the confidentiality of genetic information. However, as in the cases cited above relating to consent, a judge may decide to revoke the confidentiality of genetic data associated with an identifiable individual in situations involving proceedings for recognition of paternity or in criminal proceedings.

### **C. *Research on the Human Genome***

Articles 10, 11 and 12 of the Declaration underline the primacy of respect for human rights over research in biology, genetics and medicine. For, it cannot be accepted that the research in question and the applications flowing therefrom should pursue goals contrary to human rights, fundamental freedoms and the dignity of both individuals and groups of people, especially certain populations and minorities, or that the manner in which this research and these applications are conducted should depart from these principles.

The technologies derived from genetic engineering and biology could lead to practices, contrary to human dignity, that should not be permitted. This section mentions the example of cloning for the purpose of reproducing human beings. But other technologies are concerned, and some of them are already in use such as sex-based embryo selection or, in the more distant future, the creation of chimeras by transgenesis. International co-operation should be set up to identify other practices which, under the pretext of major general interest (for example the prospect of important therapeutic advances), lead to experiments contrary to the dignity and rights of the persons involved.

This section also recognizes the freedom of research. The International Covenant on Economic, Social and Cultural Rights of 16 December 1966 indeed states that respect for freedom is 'indispensable for scientific research and creative activity'. This is the corollary of the right that it recognizes of each individual to 'enjoy the benefits of scientific progress and its applications' (Art. 15). In the same spirit, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, invites States to display the 'utmost respect for the autonomy and freedom of research necessary to scientific progress' (Article 8).

### **D. *Conditions for the Exercise of Scientific Activity***

The UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974 affirms the 'moral, human and ecological' responsibility of researchers. Article 13 of the Declaration stresses the responsibility of researchers which is the counterpart of their freedom. The Declaration recalls the importance of the social and ethical implications of research on the human genome, which requires researchers to be particularly aware of their duties and dictates compliance with strict professional ethics (thus reinforcing the importance of formalized research protocols). It also recalls the fact that public and private science policy-makers, playing a role in scientific policy, have special responsibilities in this respect.



Articles 14 and 15 are corollaries to the previous article. They emphasize the steps that must be taken by States in order to promote a favourable context for research in genetics. The Declaration draws inspiration in this respect from the principles laid down by UNESCO in its Recommendation on the Status of Scientific Researchers of 20 November 1974. This recommendation recalls in its preamble that the improvement of the conditions of existence of humanity depends on the progress of scientific research and then, in Article 20, underlines the essential duty of States to encourage this research by providing researchers with both moral support and material assistance.

Article 15 of the Declaration stipulates moreover that States should seek to ensure that the results of research on the human genome are not used for non-peaceful purposes.

Article 16 asks the States to promote the establishment of ethics committees that will have a manifold vocation: assessing the consequences for society of advances in the life sciences and of the ethical, legal and social problems resulting therefrom; providing the authorities with information in the form of well-reasoned advice, especially in order to prevent abuses (cf. sub-paragraph (i) of Article 19); and, fostering the training and information of the public. The Declaration specifies that these committees must fulfil three conditions. They must be independent of the political, economic, scientific and especially medical authorities. Their composition must be multidisciplinary in order to enable an understanding of the diversity of the questions raised at the scientific, philosophical, legal, economic and social levels. Finally, they must be pluralistic in order to permit the expression of the main forms of ethical and cultural sensibility. It is up to the States to determine the status of these committees and the most relevant level for their institution at the local, national or regional levels.

### ***E. Solidarity and International Co-operation***

In its fifth section, the Declaration deals with international solidarity and co-operation. At the social level, advances in genetics should not jeopardize systems of assistance to individuals, families and population groups vulnerable to or affected by diseases or disabilities of a genetic character. In the face of this danger, the Declaration affirms that States should respect and promote active solidarity towards these categories of persons. With respect to questions that primarily involve privacy, the right of the individual to make up his or her mind freely cannot be brought into question indirectly, for example through the elimination of medical and social benefits or assistance. This article also seeks to prevent any risk of attaching a stigma to individuals suffering from a disease or disability of genetic origin.

By virtue of this solidarity, the States must also encourage research seeking to identify, prevent or treat genetic diseases, or diseases influenced by genetics, especially rare or endemic diseases.

### ***F. and G Promotion of the Principles of the Declaration and Implementation of the Declaration***

In line with the tasks assigned to UNESCO, these two sections are aimed at the promotion, in every country, of education in bioethics from a multidisciplinary perspective along with the research associated with it. The scope of the Declaration goes beyond the specialist groups concerned (such as doctors, researchers, health professionals, scientific and health policy managers, jurists, etc.). It seeks to address each and every individual and make bioethics an essential component of tomorrow's culture. Bioethics must integrate the scientific and technical bases needed in order to be able to ask the essential questions and promote an ethics of freedom and responsibility.

The teaching of bioethics, which must reflect the world's different currents of thought and its different cultures, is also a school of the open-mindedness and respect for others that UNESCO has to encourage. To give effect to the principles set forth, in addition to possible normative action, Article 23 emphasizes the importance of taking steps in education, training and information. It lays special stress on the need to encourage exchanges and establish networks among independent ethics committees.

The implications of research on the human genome concern not only the researchers and practitioners involved but also society as a whole. It is therefore important to encourage a wide and open international debate in order to help society take a stand on the choices raised by this research. Apart from education in bioethics, States must take steps to support other measures in the fields of research, training and the dissemination of information. The free expression of the different socio-cultural, religious and philosophical currents of thought would be indispensable in such a debate.

In regard to its implementation, the Declaration lays down in Section G entitled 'Implementation of the Declaration' that, in subscribing to the principles set forth in the Declaration, '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'. It is for the States to assess the measures most appropriate for their promotion, and these may be normative or incentive measures. In adopting the Declaration, the States solemnly recognize the importance of these principles with respect to the imperative of promoting and protecting human rights. Furthermore, the Declaration gives the International Bioethics Committee of UNESCO (IBC) the task, *inter alia*, of making 'recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and [giving] advice concerning the follow-up of this Declaration'.

*Héctor Gros Espiell*

## ***Declaration on the Human Genome***

# UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS<sup>(5)</sup>

*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 and 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,

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5. Adopted, unanimously and by acclamation, by the General Conference of UNESCO at its 29th session, on 11 November 1997.

*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>B. RIGHTS OF THE PERSONS CONCERNED</b>
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**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.

<b>C. RESEARCH ON THE HUMAN GENOME</b>
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**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.

<b>D. CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY</b>
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**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.

<b>E. SOLIDARITY AND INTERNATIONAL CO-OPERATION</b>
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**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.

<b>F. PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION</b>
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**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.

<b>G. IMPLEMENTATION OF THE DECLARATION</b>
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**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.

## **RESOLUTION ON THE IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS<sup>(6)</sup>**

*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.

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6. Resolution 29 C/17, adopted by the General Conference of UNESCO at its 29th session, on 11 November 1997.

# STATUTES OF THE INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)<sup>(7)</sup>

## Article 1

A permanent Committee, named the International Bioethics Committee of UNESCO (IBC), hereafter referred to as 'the IBC', is hereby established within the United Nations Educational, Scientific and Cultural Organization (UNESCO).

## Article 2 - Functions

1. The Committee shall have the following functions:
  - (a) it shall promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, as well as encourage the exchange of ideas and information, particularly through education;
  - (b) it shall encourage action to heighten awareness among the general public, specialized groups and public and private decision-makers involved in bioethics;
  - (c) it shall co-operate with the international governmental and non-governmental organizations concerned by the issues raised in the field of bioethics as well as with the national and regional bioethics committees and similar bodies;
  - (d) in accordance with Article 24 of the Universal Declaration on the Human Genome and Human Rights, hereafter referred to as 'the Declaration':
    - (i) it shall contribute to the dissemination of the principles set out in the Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question;
    - (ii) it shall organize appropriate consultations with parties concerned, such as vulnerable groups;
    - (iii) it shall make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of the Declaration, and it shall identify practices that could be contrary to human dignity.
2. The IBC shall determine its programme of work which shall be made public. The IBC shall include in that programme any item so requested by the Director-General or the Executive Board. It shall take into account the views of the Intergovernmental Committee, hereafter provided under Article 11, concerning its programme.

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7. Adopted by the UNESCO Executive Board at its 154th session, on 7 May 1998.

### **Article 3 - Membership**

1. The IBC shall be composed of 36 members appointed by the Director-General. The members shall be independent and shall act in their personal capacity. When making his choice, the Director-General shall take into account cultural diversity, balanced geographical representation and the need to ensure appropriate rotation. He shall also take into account the nominations for membership of the IBC received from the Member States of UNESCO, Associate Members and non-Member States which have set up a permanent observer mission to UNESCO.
2. When proposing their candidates for the IBC, states shall endeavour to include eminent persons who are specialists in the life sciences and in the social and human sciences, including law, human rights, philosophy, education and communication, with the necessary competence and authority to perform the IBC's duties.
3. The Director-General shall not appoint simultaneously more than one national of the same state.

### **Article 4 - Observers**

1. Member States and Associate Members of UNESCO may take part as observers in the meetings of the IBC.
2. Non-Member States which have set up a permanent observer mission to UNESCO may take part as observers in the meetings of the IBC on the invitation of the Director-General.
3. The United Nations and the other organizations of the United Nations system with which UNESCO has concluded an agreement providing for reciprocal representation may take part as observers in the meetings of the IBC.
4. International governmental or non-governmental organizations with similar objectives to those of the IBC may be invited to take part as observers in the meetings of the IBC.
5. Specialists or other relevant persons or groups may be consulted on matters within the competence of the IBC.

### **Article 5 - Sessions**

The Director-General shall convene the IBC at least once a year.

### **Article 6 - Terms of Office**

1. The term of office for members of the IBC shall be four years.
2. Half the IBC's members shall be replaced every two years.
3. The Director-General shall not appoint the same person for more than two consecutive terms of office.

#### Interim provision

Notwithstanding Article 6.1, the term of office of half the members appointed by the Director-General shall expire at the end of the 30th session of the General Conference. Each outgoing member shall be replaced by a national of a state belonging to the same regional group.

### **Article 7 - Advice and Recommendations**

The advice and recommendations of the IBC shall be taken by consensus, promptly made public and widely disseminated. Any member of the IBC shall have the right to record a dissenting opinion.

## Article 8 - Rules of Procedure

The IBC shall adopt its Rules of Procedure.

## Article 9 - Secretariat

1. The Director-General of UNESCO shall provide the staff and other means required for the operation of the secretariat of the IBC.
2. The Director-General shall appoint a member of the Secretariat of UNESCO as Secretary-General of the IBC.

## Article 10 - Expenses

1. The servicing expenses of the sessions of the IBC shall be financed by the appropriations allocated for this purpose by the General Conference.
2. Member States of UNESCO, Associate Members and non-Member States which have set up a permanent observer mission to UNESCO shall bear the expenses of the participation of their observers at the sessions of the IBC and of their participation in the Intergovernmental Committee.
3. UNESCO shall bear the expenses of the participation of specialists in connection with hearings requested by the IBC.

## Article 11 - Intergovernmental Committee

1. An Intergovernmental Committee, hereafter referred to as 'the Intergovernmental Committee', is hereby established within the United Nations Educational, Scientific and Cultural Organization (UNESCO).
2. The Intergovernmental Committee shall examine the advice and recommendations of the IBC, including those concerned with the follow-up of the Universal Declaration. The Intergovernmental Committee shall inform the IBC of its opinions. It shall submit its opinions to the Director-General for transmission, together with the advice and recommendations of the IBC, to the Member States, the Executive Board and the General Conference. It may transmit any proposals for the follow-up of the advice and recommendations of the IBC.
3. The Intergovernmental Committee shall be composed of 36 representatives of the Member States elected by the General Conference. Associate Members of UNESCO shall be invited to participate. When electing the members of the Intergovernmental Committee, the General Conference shall take into account cultural diversity, balanced geographical representation and the need to ensure appropriate rotation.
4. The term of office of members of the Intergovernmental Committee shall extend from the end of the ordinary session of the General Conference during which they are elected until the end of its second subsequent ordinary session.

### Interim provision

The Executive Board, at its 155th session, as an interim measure, shall elect the first members of the Intergovernmental Committee to hold office until the next succeeding General Conference. When electing these members, the Executive Board shall take into account cultural diversity, balanced geographical representation and the need to ensure appropriate rotation.

5. Member States of UNESCO, Associate Members and non-Member States which have set up a permanent observer mission to UNESCO may take part in the meetings of the Intergovernmental Committee. The provisions of Article 4 relating to the IBC shall apply *mutatis mutandis* to the Intergovernmental Committee.

6. The sessions of the Intergovernmental Committee shall be convened by the Director-General at least once every two years.
7. Where the Intergovernmental Committee or the Director-General so decides, a Joint Session of the IBC and the Intergovernmental Committee, hereafter referred to as 'the Joint Session', shall be convened. The Joint Session shall foster dialogue between the IBC and the Intergovernmental Committee on matters of mutual concern. Without limiting the generality of such matters, they may include consideration of any proposals to:
  - (a) amend the Universal Declaration on the Human Genome and Human Rights; or
  - (b) adopt any further declaration or any other international instrument within the field of competence of the IBC.

The Joint Session shall:

- (a) be chaired by the chairpersons of the IBC and of the Intergovernmental Committee as joint presiding officers;
- (b) be open to observers *mutatis mutandis* in accordance with Article 4; and
- (c) present a report on the meeting to the Director-General, who shall provide it to the Member States for such action as they may decide before it is presented to the General Conference.

## **Article 12 - Revision**

These Statutes may be revised by the UNESCO Executive Board.

## **UNITED NATIONS RESOLUTION ON THE HUMAN GENOME AND HUMAN RIGHTS<sup>(8)</sup>**

*The General Assembly,*

*Guided* by the purposes and principles set forth in the Charter of the United Nations, the Universal Declaration of Human Rights, the International Covenants on Human Rights and the other relevant international human rights instruments,

*Recalling* Commission on Human Rights resolutions 1993/91 of 10 March 1993 and 1997/71 of 16 April 1997, on the question of human rights and bioethics,

*Recalling also* that, in accordance with the Universal Declaration of Human Rights, recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

*Aware* of the rapid development of the life sciences and of ethical concerns raised by certain of their applications with regard to the dignity of the human race and the rights and freedoms of the individual,

*Seeking* to promote scientific and technical progress in the fields of biology and genetics in a manner respectful of fundamental rights and for the benefit of all,

*Emphasizing*, in this regard, the importance of international cooperation in order to ensure that mankind as a whole benefits from the life sciences, while seeking to prevent them from being used for any purpose other than the good of mankind,

*Recalling* the Universal Declaration on the Human Genome and Human Rights and the accompanying resolution on its implementation, both adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organization at its twenty-ninth session,

*Recognizing* the importance of the process of follow-up to the Universal Declaration on the Human Genome and Human Rights within the framework of the United Nations Educational, Scientific and Cultural Organization,

*Convinced* of the need to develop a life-sciences ethic at the national and international levels,

*Endorses* the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997.

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8. Resolution 53/152, adopted by the United Nations General Assembly at its 53rd session, on 9 December 1998.

***Preparatory Works of  
the Legal Commission of the IBC***



# **FIRST MEETING OF THE LEGAL COMMISSION OF THE IBC**

(Paris, 7 April 1994)

## **I. Introduction**

Welcoming the members of the Legal Commission of the International Bioethics Committee (IBC) and participants, the Chairman, H. Ex. Mr Héctor Gros Espiell, said that the main purpose of this first meeting was to examine the document on methodology<sup>9</sup>, prepared by himself, to serve as a basis in drafting an international instrument on the human genome, and to consider the draft outline of the International Association of Legal Science (IALS). That draft sets out the framework for a comparative international study which the IALS has decided to make on the state of positive law in domains affecting the protection of the human genome.

Before discussing these two points, Mrs Noëlle Lenoir, Chairperson of the IBC, wished to explain the purpose of the Legal Commission and the tasks assigned to it.

The IBC, established by the Director-General, has received the mandate to continue reflection on the preparation of an international instrument on the human genome, and to facilitate the exchange of ideas and information between North and South, East and West. The task of the IBC is, in this respect, without precedent. Although a body of international norms relating to human rights and bioethics already existed (for example, the draft framework-convention on bioethics drawn up by the Council of Europe), these international instruments differed from that which the IBC might establish in not being of universal application.

The Legal Commission of the IBC composed essentially of eminent jurists, members of the IBC, is invited to make practical proposals regarding the form and content of an international instrument for submission to the Second Session of the IBC, in September 1994. The ensuing result would be submitted by the Director-General to the General Conference of UNESCO. Thus, as part of the IBC, the role of the Legal Commission, a body for discussion, reflection, and exchanges of ideas and information between countries having different approaches and purposes, is to suggest precise guidelines with the - operational - purpose of laying down the basis of a future international instrument.

## **II. Methodology for the Elaboration of an International Instrument for the Protection of the Human Genome**

### **A. *Presentation of the Document of Methodology***

As a preliminary, the Chairman of the Legal Commission recalled that, as the 27 C/Resolution 5.15 of the General Conference did not specify any particular form, the IBC had a free choice regarding the legal nature of the international instrument it might propose.

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9. See Annex I.

It could be a declaration or a convention. It has been noted that, in United Nations practice regarding international instruments concerning human rights, most conventions have been preceded by the adoption of a declaration. Thus, the Universal Declaration of Human Rights has been followed by the adoption of the Convention on the Prevention and Punishment of the Crime of Genocide (9 December 1948), the International Convention on the Elimination of All Forms of Racial Discrimination (21 December 1965), and the two International Covenants on Human Rights (1966).

At the end of the Second World War, declarations were not considered as a source of law in the strict sense, i.e. having legal force. They were considered only as an ethical and political approach - conduct, for example, to be followed by States - so constituting the moral conscience of humankind regarding questions of human rights. Nowadays, however, some declarations were recognized both in theory and in practice as taking effect in law. Here mention might be made of a development in the theory that enhanced crystallising general legal principles. It might also be recalled that, in its advisory opinions and in disputes, the International Court of Justice referred to the Universal Declaration of Human Rights as a legal source in the fullest sense. That recognition was also reinforced by jurisprudence in the interpretation of the Charter of the United Nations.

It would accordingly be advisable to follow the already established practice of first drafting an international instrument of the declaratory type. It would already have a certain legal force, to be completed later by a convention. The declaratory instrument should be written in terms sufficiently general to maintain a certain flexibility in a domain in which science is continually advancing, and in order to transcend different cultural, political and religious sensitivities. It would be composed of a preamble recalling the principles governing the question of the protection of the human genome (human dignity, relations between ethics and science, etc.) and, in addition, a declaratory part affirming the fundamental principles applicable to the future of humankind and of every human being.

The convention is the indispensable complement of the declaration, establishing a more precisely binding engagement of the responsibility of States, international organizations, and even of individuals. It had to be remembered, however, that, in practice, the adoption and application of a convention could take several years. Thus, the preparation of the two International Covenants on Economic, Social and Cultural Rights, and on Civil and Political Rights, begun in 1948, became operative only in 1966 because of upheavals in the world brought about by economic, social and political developments, and by decolonization. The latter, moreover, led to the introduction in the two Covenants mentioned above of an element which does not figure in the 1948 Declaration: the right of peoples to self-determination.

In the matter under consideration, the time factor had a special importance that could not be overlooked. Advances in science, immediately or almost immediately applicable, were so rapid that there would inevitably be gaps between science at the time a convention was drafted, and its state when, 8 to 10 years later, it entered into force. To avoid such gaps, a draft convention, which would become applicable later, should be prepared at the same time as the declaration; but the declaration would, nevertheless, already have acquired a certain effectiveness.

On the fundamental question of content, it has to be remembered that what is involved is not the preparation of an international instrument on bioethics in general, but on the human genome in the context of safeguarding human rights. The content of the preamble and the subsequent operative articles thus remain to be determined.

For that purpose, it is essential to consult certain legal sources, and a first selection is proposed in the document on methodology given as Annex I. A study of major international instruments, universal or regional, Constitutions and domestic laws, and resolutions and recommendations put forward by international, intergovernmental and non-governmental organizations, would yield a corpus of the fundamental principles recognized by the international community that go beyond political, legal, cultural and other differences.

## ***B. Discussion on the Document of Methodology***

Before outlining the various possibilities open to the Legal Commission in regard to the choice of a possible international instrument, Mr Mohammed Bedjaoui underlined two important points: firstly, the great latitude accorded by the General Conference to the IBC in proposing the legal nature of that instrument; and, secondly, the necessity of taking account of the time factor, which must condition that choice.

The question of form remaining open, a listing should be made through a study of precedents of the different legal solutions offered by international law. Five main formulae emerge.

- i) **Adoption of a declaration only.** In the United Nations, one example of a declaration that has gained particular force is the Declaration on the Principles of International Law concerning Friendly Relations and Co-operation among States in accordance with the Charter of the United Nations (2625 (XXV)), unanimously adopted by the General Assembly of the United Nations on 24 October 1970.
- ii) **Adoption of a declaration and a convention.** Although prepared simultaneously, the drafting of a convention would take longer.
- iii) **Adoption of a convention only.** As the matter is new in international law, that solution is possible but, because of the time factor, it involves too many complications.
- iv) **Approach of the International Labour Organization (ILO).** This Specialized Agency of the United Nations system has drawn up some 167 international conventions which have obtained over 7,000 ratifications by Member States. The ILO, incidentally, has succeeded in short-circuiting the time factor by devising an original mechanism that saves time in the signature on the way up, and guarantees rapid ratification by Member States on the way back. They undertake to proceed to ratification within the 18 months following the adoption of a convention, failing which they have to justify such delays before the International Labour Conference. Each State, in addition, has a moral obligation to provide a progress report on the internal state of progress of the ratification procedure. UNESCO could adopt a similar procedure.

At that stage of the reflection, the specificity of the instrument for the protection of the human genome should be considered. What is involved is neither codification, i.e. the transcribing of a practice or custom; nor harmonization, i.e. a single text embodying international practices or legislations that are scattered or incomplete. Neither is it a question of progressively extending international law in the sense of Article 13 of the Charter of the United Nations. It is, in fact, an atypical approach to a *sui generis* situation. An international instrument on the human genome should articulate the ethical determination to so encompass advances in science that it is mankind and hence, the progress of human rights throughout the world, that they serve.

- v) For the classical approach of public international law, that last formula substitutes an **elaboration process from private international law in 'uniform law'**. It would thus propose adopting a draft convention having a single article which could be phrased in the following terms: 'The Signatory States undertake to introduce into their respective legislation the principles set forth in the model law hereby attached in annex. A Supervisory Committee, composed of Signatory States, shall be set up, who shall be informed by central administrative authorities of the conditions of application of the draft model law'.

That last formula has the advantage of introducing uniform norms in the diversity of States so as to ensure greater co-ordination while, at the same time, maintaining a certain flexibility: each State being able, in accordance with its Constitution, to adopt the most suitable legal arrangements. The supervisory committee would ensure conformity among the national legislation; it could consider practical problems arising from application, and suggest arrangements. The committee would thus be able, where necessary, to deal with legal deficiencies in the text that might not have been apparent at first, and arrange adaptations made necessary by developments in scientific research and their applications.

The Chairman of the Legal Commission, after thanking Mr Bedjaoui for his important contribution, made the following remarks concerning the first, the fourth and the last formulae.

Some declarations had, in fact, political and legal importance: Declaration 2625 (XXV), referred to above, for example. Its last article states that 'the principles of the Charter which are embodied in this Declaration constitute basic principles of international law'. That allowed theory to develop *juris commis*. The same applies to the United Nations Declaration on the Right to Development of 4 December 1986.

The ILO formula could be adopted as, in conventions, it cuts out the stage of signature and introduces an efficient system for the control of ratifications by Member States.

Finally, public international law procedures could be combined with those of private international law in elaborating a declaration while, at the same time, preparing a draft single article convention referring back, in annex, to a draft uniform law and foreseeing the creation of a supervisory committee.

The Chairperson of the IBC made a number of comments regarding the form of a future international instrument.

Everyone agrees that the time factor is of essence, all the more so as the IBC might fix 1998 - jubilee year of the Universal Declaration of Human Rights - as the date for the adoption of an international instrument.

For its first stage, the declaratory formula is undoubtedly most suitable; it allows account to be taken of the imperative of time without at the same time being foregoing all legal force. For certain States it might even provide a source of law via a jurisprudence founded on their Constitution. However, the formula of a real international convention (treaty) should not be lost sight.

UNESCO is ideally situated to provide follow-up: such an instrument is inconceivable without a follow-up mechanism.

With regard to the substance, Mrs Lenoir pointed out that the content of the instrument would constitute a source of principles of interpretation for national authorities and, accordingly, for normative law. But its immediate objective could not be the harmonization of all the national regulatory systems: that task would be too delicate because of the disparity of legislation (where they do exist), reflecting, as they do, different political or cultural sensitivities. The Chairperson further pointed out that the term 'protection of the human genome' demanded clarification. It could, in fact, as in the United Nations Convention on Biological Diversity (June 1992) be considered from the point of view of sharing knowledge derived from research and the economic fallout from research (data and information banks, industrial property, patents); that is already partly the case with the World Trade Organization. In a first acceptance, the principle of solidarity should come first. The protection of the human genome should also, and above all, be based on human rights - essentially respect for individual freedoms, and non-discrimination.

The representative of the World Health Organization (WHO) recalled that, for almost 15 years, WHO has preferred to intervene in ethical and scientific matters via recommendations. Between 1978 and 1981, WHO had considered problems of sales of infant foods. Rather than adopting compulsory regulation, WHO had finally preferred to establish an international code of conduct, now adopted by most States. That text, 10 years later, inspired the code of milk substitute sales adopted in Brussels. Similarly, in 1991, the World Health Assembly had, by resolution, adopted guiding principles relating to human organ transplantation and invited Member States to take those principles into account in drawing up their policies on human organ transplantation.

Mr Bedjaoui recalled that the existence of a date limit ensured that the time imperative was duly considered. The IBC should therefore choose the most adequate instrument from the legal arsenal available; that procedure, reinforced by precedents, would thus become more precise and rapid.

Mr Bedjaoui also pointed to the advisability of combining the various formulae referred to; the single article might be completed by a preamble, and it might be preferable to speak of 'guiding principles' rather than a 'model law'.

Mr Mohammed Bennouna, referring to the questions of methods, suggested that the opposition between declaration and convention should not be overestimated. The strength of an international instrument depends to a large extent on its content. If it is weak, or does not enjoy consensus, its impact, whatever its form, would be limited. Text conformity is not desirable either since legislation on the subject is mostly embryonic. It would be better, in a declaration, to set out a number of relevant fundamental principles - for example, consent, non-commercialisation of the human body and its components, scientific research, the common heritage of humankind, etc., which could serve as a guide for national legislation. Although such a declaration would have no legal force in the strict sense it could have an impact because of publicity about it, and become a generally known reference. It is accordingly vital that the declaration should receive a solemn and unanimous proclamation.

Mr Otakar Motejl also spoke in favour of a declaration setting forth the major principles regarding the protection of the human genome. In a domain where development is rapid and it is difficult to be sure about its direction, there is a danger in defining too rigidly and definitively elements which would not evolve as rapidly as research in science. A declaration mainly devoted to the great general principles, and intended to guide the elaboration of national legislation, would permit a better adaptation to scientific progress. Such an instrument would be easier to introduce into Czech law, in pursuance with Article 10 of the Constitution, which recognizes the primacy of international instruments ratified by the Czech Republic in its domestic law.

Mr Daniel de San intervened to inform the Commission of UNESCO's experience with follow-up procedures. Certain UNESCO instruments obliged States to present reports to the bodies competent for ensuring their application. The results are not always what they might be. A mechanism should therefore be introduced in the instrument to insure follow-up. The IBC could, in an appropriate form, assume that role.

Mrs Lenoir raised the question of the absence or the multiplicity of definitions regarding the protection of the human genome. Should the ideas of consent or of eugenics be defined? What do we understand by genetic resources or genetic heritage? She pointed out that the instrument would have a pioneering role, as it would translate scientific ideas into legal concepts which law did not as yet perfectly apprehend. She also pointed out, that in that regard, international law often preceded domestic law and that complicated the task of the IBC and imposed a heavier responsibility.

The discussion also gave rise to several questions. Should the international instrument define only the terms used? Should it not, as a minimum, define the purpose of its instrument in the preamble, namely, the very idea of the concept of the 'protection of the human genome'? In view of the experience of WHO, is it wiser not to attempt any definition?

### **C. Conclusions**

Everyone agreed that a declaration should be adopted first, but it remained to be decided whether, in parallel, a convention on classical lines or on the model of international private law should be prepared.

The methodology document was merely an outline and was to be complemented on the following points:

- the most appropriate mechanism for adopting the proposed instrument in question;
- the importance of the time factor: a first analysis of legal sources (including the Convention on Biological Diversity) which should serve as a model;
- a proposal regarding the ethical-legal scope of the international instrument and an outline of its possible contents.

Those points would be covered in the methodology document to be submitted to the next meeting of the Legal Commission.

## **III. Draft Detailed Plan of the International Association of Legal Science (IALS)**

The draft detailed plan submitted by the IALS could serve as a framework for national reports, prepared by specialists, on the state of the law in matters affecting the protection of the human genome, with a view to preparing a comparative international study.

It was recalled that the selection of countries in which the survey would be made should satisfy two criteria:

- to ensure the international character of the comparative study, care should be taken to ensure that the different legal systems and cultures of the world be represented;

- it must be possible, in the various countries, to count on relays such as national ethics committees or national ethics institutes, and on legal institutions and/or experts who could ensure the collection and analysis of the information requested.

This study shall be carried out through external financing and shall depend upon obtaining it. Preliminary results of the study, to be completed in 1995, would be submitted to the second session of the IBC, as part of the examination of the work of the Legal Commission.

The Chairman of the Legal Commission thanked the IALS for its co-operation in the legal work of the IBC, and invited the members of the Commission to get in touch with the association in order to communicate any comments they might wish to make on the detailed plan.

#### **IV. Closing of the First Meeting of the Legal Commission**

After thanking all the participants for their contributions, the Chairperson recalled that the second meeting of the Legal Commission would take place on Thursday 9 June 1994.

# METHODOLOGY FOR THE PREPARATION OF AN INTERNATIONAL INSTRUMENT FOR THE PROTECTION OF THE HUMAN GENOME

(Paris, 2 June 1994)

*by Héctor Gros Espiell*

## I. Choice of the Legal Nature of the Possible International Instrument for the Protection of the Human Genome

### A. *Preliminary Remarks*

#### Importance of the Time Factor

In the matter under consideration, the time factor has a special importance that could not be overlooked. Advances in science, immediately or almost immediately applicable, are so rapid that there would inevitably be gaps between science at the time an international instrument is drafted and its state when it enters into force.

The IBC has fixed the year 1998, Jubilee Year of the Universal Declaration of Human Rights, as the date for the adoption of the international instrument. The next General Conference, in 1995, should give a mandate to the Director-General to prepare a draft of this international instrument. On this basis, in 1996 and 1997, the IBC will draw up a preliminary draft of this instrument that will be presented for adoption in 1998.

#### Choice of the Legal Nature of the International Instrument

The IBC disposes of a great latitude in proposing the legal nature of the international instrument, as the resolution of the General Conference does not specify any particular form.

### B. *Elements for a Choice*

Five main formulae emerge from the mechanisms developed by the practice of the international law.

**Adoption of a declaration only.** In the United Nations, an example of a declaration that had, in fact, political and legal importance is the Declaration on the Principles of International Law concerning Friendly Relations and Co-operation among States in accordance with the Charter of the United Nations (2625 (XXV)), unanimously adopted by the General Assembly of the United Nations on 24 October 1970. Its last article states that 'the principles of the Charter which are embodied in this Declaration constitute the basic principles of international law'. This has permitted the theory to develop the concept of *juris commis*. The same applied to the Declaration on the Right to Development of 4 December 1986.

**Adoption of a declaration and a convention.** It would accordingly be advisable to follow the already established practice of first drafting an international instrument of the declaratory type; it would already have a certain legal force, to be completed later by a convention. The declaratory instrument should be written in terms sufficiently general to maintain a certain flexibility in a domain in which science is continually advancing, and in order to transcend different cultural, political and religious sensitivities. It would be composed of a preamble recalling the principles governing the question of the protection of the human genome and a declaratory part affirming the fundamental principles applicable to the future of humankind and of every human being.

It should be remembered, however, that, in practice, although prepared simultaneously, the adoption and application of a convention could take several years. Thus, the elaboration of the two International Covenants on Economic, Social and Cultural Rights, and on Civil and Political Rights, begun in 1948, became operative only in 1966 because of upheavals in the world brought about by economic, social and political developments, and by decolonization.

**Adoption of a convention only.** As the matter is new in international law, this solution is possible but, because of the time factor, it involves too many complications.

**Approach of the International Labour Organization (ILO).** This specialized Agency of the United Nations system has drawn up some 167 international conventions which have obtained over 7,000 ratifications by Member States. The ILO, incidentally, has succeeded in short-circuiting the time factor by devising an original mechanism that saves time in the signature on the way up, and guarantees rapid ratification by Member State on the way back. They undertake to proceed to ratification within the 18 months following the adoption of a convention, failing which they have to justify such delays before the International Labour Conference. Each State, in addition, has a moral obligation to provide a progress report of the international state of progress of the ratification procedure. UNESCO could adopt a similar procedure.

The last formula substitutes the classical approach of international public law with an **elaboration process from private international law in 'uniform law'**. It would thus propose adopting a draft convention with a single article which could be phrased in the following terms: 'The Signatory States undertake to introduce into their respective legislations the principles set forth in the model law hereby attached in annex. A Supervisory Committee, composed of Signatory States, shall be set up, who will be informed by central administrative authorities of the conditions of application of the draft model law'.

This last formula has the advantage of introducing uniform norms in the diversity of States in order to ensure greater co-ordination while, at the same time, maintaining a certain flexibility: each State being able, in accordance with its Constitution, to adopt the most suitable legal arrangements. The Supervisory Committee would ensure conformity among the national legislations; it could consider practical problems arising from application, and suggest arrangements. The Committee would thus be able, where necessary, to deal with legal deficiencies in the text that might not have been apparent at first, and arrange adaptations made necessary by developments in scientific research and their applications.

### **C. Chosen Form**

For this first stage, the declaratory formula is undoubtedly the most suitable, it allows account to be taken of the imperative of time without at the same time being foregoing all legal force. For certain States it might even provide a source of law via a jurisprudence founded on their constitution. But the formula of a real international convention (treaty) should not be overlooked.

The convention is the indispensable complement of the declaration, establishing a more precise binding engagement of the responsibility of States, international organizations, and even of individuals.

Public international law procedures could be combined with those of private international law in elaborating a declaration while, at the same time, preparing a draft convention. It remains to be decided whether the convention, in parallel, should be prepared on classical lines or on the model of international private law.

UNESCO is ideally situated to provide a follow-up: such an instrument is inconceivable without a follow-up mechanism.



## II. Content of the Possible Instrument

### A. *Necessity of a Preamble*

It is indispensable that the instrument which could be adopted give ample space to the preamble.

The necessity and the importance of a preamble stating in general terms the objectives and underlying principles common to the entire humanity is justified by the two following reasons:

- the specificity of this international instrument, which deals with a subject where the accelerated progress of research is applied almost immediately;
- the instrument intervenes in a very sensitive area on account of its cultural, religious, political and ethical dimensions.

### B. *Principles Which Should Figure in the Preamble*

The principles on which the instrument is based and its objectives should figure in the preamble.

In order to define the universal common principles which should appear in the preamble, it is necessary, first, to define from positive law, the principles already recognized by the various States and that concern the human genome. The following principles can be summarized:

- a. **the status of knowledge:** freedom of research, security of researchers, requirement of special care in the presentation of information and the principles of the responsibility of the researchers;
- b. **the protection of the human being:**
  - i) identity of the human being, the principle of the equal dignity of individuals of the human species,
  - ii) integrity of the human being, right to life/right to live, right to health, human dignity,
  - iii) freedom of will and the principle of free and informed consent,
  - iv) the protection of privacy and of family life, the confidentiality of individual data;
- c. the principle of **solidarity**;
- d. the principle of **non-discrimination**; and,
- e. the principle of **non-patrimonia**lity and of **non-commercialization** of the human body.

### C. *Question of the Absence or the Multiplicity of Definitions*

The instrument prepared by the IBC would have a pioneering role, as it would translate scientific ideas into legal concepts which law does not as yet perfectly apprehend.

Three questions must be solved:

- Should it not, as a minimum, define the purpose of its instrument in the preamble, namely, the very idea of the concept of the 'protection of the human genome'? The term 'protection of the human genome' must be clarified. It could, in fact, like the United Nations Convention on Biological Diversity (June 1992) be considered from the point of view of sharing knowledge derived from research, and the division of the economic fall-out from research (data and information banks, industrial property and patents). That is already partly the case with the World Trade Organization. In a first acceptance, the principle of solidarity should come first. The protection of the human genome should also, and above all, be based on human rights, essentially respect for individual freedoms and non-discrimination;
- Should the ideas of consent of eugenics be defined? What do we understand by genetic resources or genetic heritage?
- Should the international instrument define only the terms used in that text?

### **III. The Ethical and Legal Scope**

The strength of an international instrument depends to a large extent on its content. If it is weak, or does not enjoy consensus, its impact, whatever its form, would be limited.

It would be better, in a declaration, to set out a number of fundamental principles related, for example, to consent, non-commercialization of the human body and its components, scientific research, the common heritage of humanity, etc., which could serve as a guide for national legislation. Although such a declaration would have no legal force in the strict sense it could have an impact because of publicity about it, and become a generally known reference. It is thus essential that a declaration is solemnly and unanimously approved.

The content of the instrument would constitute a source of principles of interpretation from national authorities, and accordingly, for normative law. But its immediate objective could not be the harmonization of all national regulatory systems: that task would be too delicate because of the disparity of legislations (where they do exist), reflecting as they do, different political cultural sensitivities.

# **SECOND MEETING OF THE LEGAL COMMISSION OF THE IBC**

(Paris, 9 June 1994)

## **I. Introduction**

The Chairperson of the International Bioethics Committee (IBC), in welcoming the members of the Legal Commission and personalities associated with its work, expressed her deep regret that H. Ex. Mr Héctor Gros Espiell was unable to attend this meeting due to his pressing professional commitments. She also referred to the absence of Mr Otakar Motejl, President of the Constitutional Court of the Czech Republic, who had also apologised for similar reasons.

Then she announced the timetable of the Legal Commission's work until the Second Session of the IBC in September 1994.

The Chairperson of the IBC made the reminder that this session would be open to the general public, and especially to the press. She indicated that certain specific contributions coming from members of the IBC had reached Mr Georges Kutukdjian and that they would be used as part of the Committee's report distributed at the next session. The exact contents of the documents to be distributed will be outlined later.

## **II. Preparation of an International Instrument on the Human Genome**

There was a discussion on the procedure to follow in order to elaborate a declaration to be adopted by UNESCO, which would precede the adoption of a convention.

It was stressed that it would be timely, before deciding on the main lines of the text to be established for the second session of the IBC in September 1994, that a first draft of a text be circulated for comments among a large number of authorities all over the world: international liaison officers of the IBC (governmental and non-governmental organisations, foundations), national ethics committees, etc.. This system of 'fundamental codification' seems all the more necessary in practice since it will, while embracing principles of universal value, take into account the diversity of cultures, the preoccupation and aspirations of populations in different countries and continents. Furthermore, one of the major objectives of the IBC is to set back the debate on ethics into a planetary context, by giving the opportunity to representatives of countries from the South to voice their concerns, often neglected in such discussions.

That is not to say that a declaration should be drafted prematurely. This declaration needs to elicit ample discussions within UNESCO as well as at the level of States, members of the Organization or having an observation status.

### III. Timetable

Mrs Noëlle Lenoir suggested the following order:

- **22 September 1994:** adoption by the IBC, based on the proposal of its Legal Commission, of a recommendation taking position on the suggested juridical form for the international instrument on the human genome and on the guiding guidelines proposed for this instrument;
- **October 1994:** transmission of the recommendation (together with the relevant report) to the Director-General of UNESCO;
- **December to May 1994-1995:** organization and animation of the debate on the two documents cited earlier by way of hearings of personalities, from different disciplines and in different countries, and of consultations (questionnaire, survey, etc.);
- **June 1995:** third session of the IBC. Adoption of a synthesis document to be presented to the General Conference of UNESCO in the fall of 1995;
- **October to November 1995:** decision of the General Conference on the opportunity and the form of the planned international instrument;
- **1996:** finalization by the IBC of a preliminary draft of the declaration, based on the decisions of the General Conference, to be adopted in 1996, year of the 50th anniversary of UNESCO. The preliminary draft of the convention should be ready for adoption in 1998, year of the 50th anniversary of the Universal Declaration of Human Rights, following usual procedures in the matter.

### IV. Scope and Content of the International Instrument

As far as the scope of the future declaration is concerned, it should be kept in mind that:

- a declaration, in principle, does not have any binding juridical force but it could yield great moral influence, especially if it were adopted by unanimity. Nevertheless, the adoption of international instruments at UNESCO, in general, only requires a simple majority within the General Conference, the sovereign body of the Organization;
- certain declarations have a quasi-normative purport (see the Universal Declaration of Human Rights of 1948) which does have a juridical impact on national and international jurisprudence;
- UNESCO has adopted many recommendations and declarations some of which state principles which are likely to be included into a text on bioethics (for example, the Declaration of the Principles of International Cultural Co-operation of 1966, the Recommendation on the Status of Scientific Researchers of 1974, the Declaration on Race and Racial Prejudices of 1978).

In order for the declaration to have some real impact, it is necessary to foresee a monitoring and follow-up mechanism, the structure of which should possess the most efficient means for this purpose. A study will be prepared on the types of mechanisms foreseeable in terms of their relevance and their efficiency.

As far as the contents of the declaration is concerned, it should consist of an important preamble, stating all the important texts of reference and detailing its field of application and its objectives.

This preamble should be followed by a statement of principles taken mostly from important reference texts on bioethics. These principles could reflect an ontological approach (the notion of human dignity, for example, echoing the concept of the human being as its own value) as well as a more pragmatic approach, illustrated, in particular, by the search for balance between the necessity of scientific progress and the imperative of safeguarding human rights.

There is no question, however, of taking a stance in the theoretical debate about the existence or non-existence of international principles deriving from 'natural' law, imposing respect for the rights of the individual and of the human species. Nevertheless, it is on this idea of respect of humankind that the future international instrument of UNESCO should be based.

## V. Discussion

Several strong points have emerged from the discussion forming the fundamental principles of bioethics.

### ***Respect of Human Dignity***

The aim is not only to protect the individual, in his rights and his freedoms, since dignity concerns the human being as such, in its largest sense.

Is this principle geared specially towards protecting human life? Should one go as far as to enshrine, in the field of human genetics, 'the right to life'? The answers vary according to legislations and cultures. Indeed, brain death is not accepted in all countries; 'the right to life' may be interpreted to be an obstacle to the voluntary interruption of pregnancy which is accepted, under certain conditions, in many countries.

Also, the relevance of the notion of 'the right to life' is doubtful pertaining to the subject of the future international instrument, i.e. the human genome. For the genome in itself does not correspond to the usual definition of life, since the DNA of an individual can be analysed thousands of years after his death. That is why, at present, it seems preferable not to mention 'the right to life' in the context of human genetics.

### ***The Principle of Non-Discrimination***

If it is true that any attempt to explain an illness and *a fortiori* a patient's behaviour can be a source of exclusion, the principle of non-discrimination has its rightful place in a text on human genetics and human rights. What should be the extent of its use? Without any doubt it should not be used to stop certain research whose ends seem to reflect discriminatory assumptions (research on genes of social deviance, of intelligence, etc.). To restrain the freedom of research for such types of reason would be too risky.

### ***Individual Freedom***

It is one of the most important principles. It covers the demand for a 'free and informed' consent to treatment, to research, to the gathering of individual data, etc..

The other essential component of individual freedom is linked to the right to privacy, to confidentiality of genetic data pertaining to an individual.

The emergence of predictive medicine poses in new terms the question of confidentiality of individual genetic data.

Does the assertion of the right to know lead also to recognising the right not to know? Should a doctor be allowed to reveal, in some cases, to the patient's family certain information which can have a consequence on, for example, reproductive choices? This debate is similar to that, very acute at the moment in the world, of lifting medical secrecy concerning seropositive persons and AIDS patients.

Lastly, there is the question of the legitimacy of constraints imposed by governments on individuals in the way of mandatory screening campaigns (see the new proposal for Chinese legislation, which should be put in the context of demographic control measures particular to this country; see also the examples in India, in Cyprus, etc.).

### ***The Freedom of Research and the Right to Share in Scientific Advancement and its Benefits***

Already affirmed in various declarations of the Organization, these freedoms should be solemnly re-stated as integral parts of human rights.

They are in general included in the above declarations, from the affirmation of the principle of the right to the protection of moral and material interests resulting from any scientific, literary or artistic production. UNESCO seems most competent in the matter of copyright and related rights (see the Universal Convention on Copyright of 1952). As for patents, it is rather the World Intellectual Property Organization (WIPO) which is competent in dealing with the questions of industrial protection of inventions.

As far as the genome is concerned, protection systems do overlap. Computerized data banks are often governed by regulations inspired by that of copyright, whereas the question of patenting natural genes involves the ethics of basic research. It would not be realistic for the IBC to take on the question of patents blatantly, since it is one of the subjects under study by the newly-created World Trade Organization (WTO). If it may seem timely that the instrument prepared by the IBC mentions the conflict between the right of intellectual and industrial property and the right of access to scientific and technical information, it would be advisable to find inspiration in certain provisions of the United Nations Convention on Biological Diversity of June 1992 (notably Articles 16 and 17).

Another principle comes into question while discussing the freedom of research. It is that of the protection of human research subjects, which involves their freedom to accept (or not) experimentation, and which justifies the intervention of an ethics committee whose mission is to evaluate the procedure of the research in question. Also, the Opinion formulated by the National Consultative Ethics Committee for Health and Life Sciences of France (CCNE) (Mrs Genevieve Barrier's Report, 1992) deserves to find a place in the text to be proposed by the IBC. Indeed, all research should respect the regulations of protection of the rights of human subjects regardless of the country where the experimentation is taking place.

### ***The Reliability and the Quality of Health Services and Products Resulting from Genetics***

The considerable industrial and financial stake of the development of biotechnology on a world-wide basis justifies amply the reminder to governments of the necessity of strict quality control of health services using biotechnology (tests, medicine, vaccines, etc.).

### ***Rights and Allowances***

A link should certainly be established between the protection of the human genome and certain rights and benefits: rights of the child (United Nations Convention on the Rights of the Child of 1989), of the mother, of the family, the right to health, etc..

However, the idea of the right 'to procreate', i.e. the right to have children, does not seem to be retained on the agenda.

### ***Affirmation of Duties and Responsibilities of Individuals***

The principle should be kept in a form which has yet to be determined, since the provisions of Article 29 of the Universal Declaration of Human Rights do not seem appropriate in this circumstance. Nevertheless, the notion of collective solidarity between individuals, groups and communities should be highlighted, as well as the idea of the sharing of knowledge and of wealth.

## **VI. Conclusion**

After having thanked the participants for their contribution, the Chairperson of the IBC recalled that the report would be sent to the members of the IBC in view of the third meeting of the Legal Commission, to be held on 19 September 1994.

# PROJECT OF AN INTERNATIONAL INSTRUMENT FOR THE PROTECTION OF THE HUMAN GENOME

(12 September 1994)

*by Héctor Gros Espiell*

The General Conference of UNESCO, by its Resolution of 15 November 1993, invited the Director-General 'to continue in 1994-1995 the preparation of an international instrument for the protection of the human genome'.

This same resolution of the General Conference approved the creation of the International Bioethics Committee (IBC) by the Director-General.

This Committee, created on a decision by the Director-General, is the first institution of its kind in the world and was established on 15 September 1993. The installation of this Committee was preceded by a phase of preparatory studies by a scientific and technical orientation group, constituted in December 1992 and which met eight times between January and July 1993.

The Report of Mrs Noëlle Lenoir to the Director-General, dated 15 July 1993, concluded with the following concepts which, in my opinion, should be part of this Report:

The work of the orientation group and the present report would suggest that the time has come to draft an international standard-setting instrument, based on the principles of ethical reference, ... concerning:

- the status of knowledge;
- protecting the human being;
- safeguarding the human race;
- educating, training and informing the public.

The responsibility mankind must assume today for the world of tomorrow is one of IRREVERSIBILITY. What human intervention produces, forms and recreates, dictates the future of all mankind, for as Einstein said: 'We shall have the destiny we deserve'.

This should be the inspiration for the continuity of the work of UNESCO's International Bioethics Committee.<sup>(10)</sup>

## **I. The Legal Commission**

At the first session of the IBC, the Chairperson of the Committee announced the creation of a Legal Commission, presided by H. Ex. Mr Héctor Gros Espiell, 'in order to study the conditions of the elaboration of the future international instrument for the protection of the human genome'.

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10. See 'Report of Mrs Noëlle Lenoir to the Director-General on the Human Genome', in UNESCO, *Proceedings 1994 of the International Bioethics Committee*. Paris: UNESCO, 1994.

During the first session I presented a report on the rules of law regarding bioethical questions which can be summarized in the following manner:

Mr Gros Espiell, asking what type of law should be used to deal with questions of bioethics, pointed out that without law civilized life in common was impossible. Bioethics must thus be regulated by law. Nevertheless, the boundaries between national and international law were imprecise and varied at different levels. The extension of international law was a phenomenon that went hand-in-hand with the growing realization that humankind had a common destiny. In bioethics, it would be inconceivable to establish legally binding regulations without simultaneously involving international and national law. The preparation of a future international bioethics instrument implied reference to both types of jurisprudence: national and international law.

There were several possibilities as far as the future instrument is concerned. The classical method was to start by preparing a declaration, to be subsequently adopted by the UNESCO General Conference or by the General Assembly of the United Nations; a convention or international treaty followed. The best example was the 1948 Universal Declaration of Human Rights, which was followed in 1966 by two Covenants, one in civil and political rights, the other on economic, social and cultural rights. Those two Covenants were open for signature and ratification, and entered into force only in 1976. The process of signature and ratification was extremely slow. In view of the large number of Member States and the multiple ratifications required, it usually took 10 to 15 years for a convention to enter into force. Mr Gros Espiell therefore proposed the simultaneous approval of a declaration which would enter into force on its adoption, and a convention which, on the other hand, would become effective later in time. The declaration, which could be implemented in Member States on its adoption, could also serve as a source of law for international jurisdiction.

All dogmatism must be avoided in drafting the contents of the declaration and convention. The document should be pragmatic, and open to changes that scientific progress might impose. Both instruments must take full account of cultural and religious diversity but be based at the same time on the high universal principles that originate in human dignity.<sup>(11)</sup>

The fruitful debate following my report was the basis of the main guiding principles of the work of the Legal Commission of the IBC.

## II. The Work of the Legal Commission

The Legal Commission, at its first meeting of 7 April 1994, gave us the occasion to examine all the possibilities concerning the drafting of an international instrument for the protection of the human genome.

Since April 1994, each of the three meetings of the Bureau of the IBC was preceded by a meeting of the Legal Commission.

At the second meeting of the Legal Commission, on 9 June 1994, the different criteria concerning the form and contents of an eventual international instrument for the protection of the human genome were established.

On the basis of these criteria and underlying principles, the Chairperson of the IBC and the Chairman of the Legal Commission have prepared a preliminary outline of an international instrument<sup>(12)</sup> which will be presented at the Second Session of the IBC (Paris, 20-22 September 1994).

It is thanks to the essential collaboration of Mr G. Kutukdjian, General-Secretary of the IBC, and of a group of jurists, to whom I wish to express all my gratitude, that the drafting of the preliminary outline could be carried out.

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11. See 'Report of the First Session of the International Bioethics Committee', in UNESCO, *Proceedings 1994 of the International Bioethics Committee*. Paris: UNESCO, 1994.

12. See Annex II.



Before entering into details of the main points of this draft proposal, on its principles and its objectives, on its form and its content, I wish to point out that this instrument is inspired by ideas which formed the foundation of all the actions of the IBC and which Mrs Noëlle Lenoir expressed so well in her introductory speech at the first session:

In what spirit do I see our mission? This will be my conclusion. Two key words, it seems to me, should inspire our action: Humility, Tolerance.

**Humility**, as we do not know what tomorrow will bring, what science and the relations between nations have in store for us.

In a field as evolutive as genetics and as sensitive and emotional as bioethics, we of course should not adopt a peremptory point of view. We are open to the preoccupation of each and everyone throughout the world. We must aim above all for understanding from North to South, from East to West, before deciding, if necessary, to disapprove.

**Tolerance**, even if it were not an absolute imperative, we would in any case be governed by the composition of our International Bioethics Committee, a reflection of 'the divine diversity of the world'. To define values in common, which will be one of our goals, should not lead to an erasing of our cultural differences which constitutes the richness of humanity.

In his *Memories of an European*, the Austrian writer S. Zweig wrote in 1944: 'Tolerance, far from being a sign of slackness or weakness, should be considered very highly as an ethical force'.

If only we could transmit this message to future generations and to contribute within our means of action to base the progress in life sciences on Humanism, we would not have worked in vain.<sup>(13)</sup>

### III. Analysis of Various Alternatives of Form and Content of the International Instrument

The Legal Commission has studied the different possibilities for the nature and the form of the international instrument that it is to elaborate.

Since the Resolution of the General Conference does not give any precision on the type of international instrument to prepare, we can envisage all possibilities which are compatible with international law, which is why the Commission has thought of all possible formulae in all different directions.

All possible alternatives were examined during the discussions, for example, to prepare simultaneously a declaration and a convention open to signature with its adoption, a declaration and a convention *a posteriori*, a convention with a procedure of approval and ratification analogue to the International Labour Organisation conventions and a convention with criteria analogue to those of common law, in the case of an international private law convention.

We have finally opted for a draft declaration, but in giving to the content a special characteristic - taking into account the evolution and the actual state of practice, of jurisprudence and of doctrine - which gives to this text an immediate applicability, binding legal effect and a procedure to verify its use and its efficiency.

Naturally this option does not exclude the possibility of a future convention, which will accentuate and specify legal obligations, as well as determine and concretize responsibilities and the system of verification.

Given that rapidity is the essential temporal element in the application of this international instrument, we have therefore opted for a declaration, which by its existence as such will have effect from the moment of its adoption.

The choice for a quick implementation of the international instrument should be preferred.

In the field of the human genome, the temporal factor has a particular importance. The extreme acceleration of progress in the field of molecular biology and the considerable advances made in research devoted to the genetic 'I.D. card' make it necessary for a rapid adoption of the proposed international instrument otherwise the state of law at the time of the signature of the instrument may be obsolete at the date of its enforcement.

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13. See *Proceedings 1994 of the International Bioethics Committee*. Paris: UNESCO, 1994.

On the other hand, the IBC has fixed 1998 as the deadline for the adoption of the international instrument, the jubilee year of the Universal Declaration of Human Rights. The next session of the General Conference, in autumn 1995, will decide on the opportunity and the form of the instrument that the IBC will have submitted beforehand to the Executive Board. On this basis, the IBC has only two years, 1996 and 1997, to make up a first draft of this instrument.

The elaboration of a draft convention at a later stage - and not simultaneously at the draft of a declaration - would have the advantage of benefiting from scientific progress which will take place after the adoption of the declaration, the premises of international law, and above all the experience of the application of the declaration, the questions and reactions which it will have provoked.

This procedure would take into account the process of drafting, of signature, of ratification and of enforcement of a convention, with all its characteristics - and which the contemporary doctrine has emphasized in comparing the content of a declaration with its later conventions (as in the case, among others, of the Universal Declaration of Human Rights, of the two International Covenants, and of the Optional Protocol to the International Covenant on Civil and Political Rights). Since the political and legal situation today is different than the one in 1948, we have to prepare a document of declaration with special characteristics concerning the nature of the matter which is the object of this legal regulation, of the state of international law on the theme of the legal sources, of legal value of declarations adopted by international intergovernmental organizations under certain conditions.

## **IV. Sources taken into Account for This Work by the Legal Commission**

### ***In the Matter of the Protection of Human Rights***

#### Conventional Instruments

*UNITED NATIONS:* International Covenants on Civil and Political Rights and Economic, Social and Cultural Rights of 16 December 1966; Convention on the Elimination of All Forms of Racial Discrimination (1965); Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984); International Convention of Rights of the Child (1990); Convention on Biological Diversity (5 June 1992);

*UNESCO:* Convention against Discrimination in Education (1960); Convention on the Protection of Cultural and Natural World Heritage (1972);

*Regional Organizations:* European Convention on Human Rights (1950); American Convention on Human Rights (1969); African Charter of Human and Peoples' Rights (1981).

#### Declarations and Recommendations

*UNITED NATIONS:* Universal Declaration of Human Rights (1948); Declaration on the Elimination of All Forms of Racial Discrimination (1963);

*UNESCO:* Declaration on the Principles of International Cultural Co-operation (1966); Declaration on Race and Racial Prejudices (1978).

### ***In the Area of Medical Ethics***

#### On the International Level

- Code of Nuremberg (1947); Declaration of Helsinki (1964), revised in Tokyo (1975) then in Venice (1983), adopted by the World Medical Association (WMA); Declaration of Manila (1988) made jointly by the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS); Declaration of Inuyama (1990) adopted by the Conference of the CIOMS; Declaration of Ixtapa (1994) adopted by the Conference of the CIOMS; Declarations of Valencia relative to the Human Genome Project (1988) and concerning Ethics and the Human Genome Project (1990), from work done in workshops on

international co-operation relative to the Human Genome Project, organized by UNESCO; Declaration of Moscow (1991) adopted at the 'International Meeting on Bioethics and the Social Consequences of Biomedical Research' organized by UNESCO; Declaration on Gene Patenting (1992) adopted by the International Council for Science (ICSU); Declaration of Caxambu (1992) adopted at the North-South Meeting on the human genome organized by UNESCO.

#### At the Regional Level

- We can quote the Recommendation adopted by the Council of Europe on Medical Research on the Human Being (1990), on Genetic Screening and Testing (1990 and 1992) and the Draft Outline-Convention on Bioethics (1994).

#### ***In the Area of Protection of Scientists and Freedom of Research***

The previously quoted texts relevant to medical ethics often refer to the principle of freedom of research. We can more specifically mention the UNESCO Recommendation concerning the Protection of Scientific Researchers (1974).

### **V. The Character of the International Instrument in Preparation**

No international instrument related to this topic has been adopted to this date.

Nevertheless, the Resolution 1993/91 of March 1993 of the United Nations Commission for Human Rights treated the subject 'Bioethics and Human Rights', and the Council of Europe elaborated a Draft Outline-Convention on Bioethics.

Nevertheless, these two texts do not have the same scope as the one called for by the General Conference of UNESCO. The resolution of the United Nations Commission for Human Rights did not treat specifically the problem of the protection of the human genome and did not try to be standard-setting. The unprecedented character of the Draft Outline-Convention of the Council of Europe, although it permits it to shed light on certain questions, obviously cannot give it the universal vocation required of the instrument prepared by the IBC.

On the other hand, the United Nations World Conference on Human Rights held in Vienna, 14-25 June 1993, did not give priority to bioethics, even if it is there that this subject made its first appearance (Part I, paragraph 11, 3rd subparagraph).

On the other hand, it is important to emphasize that the texts of the previously quoted Declarations of Valence and Caxambu are very short and that these conclusions could not be considered as instruments of the declarative type in international legal practice.

UNESCO is undertaking an ambitious procedure today to adopt an international instrument on the protection of the human genome:

- the aim and principles of UNESCO make it a privileged place for the elaboration of the first international instrument with a universal vocation for the protection of the human genome and should permit it to apprehend the stakes involved;
- the essential aim of this work being the protection of human rights and dignity and the reminder that the beneficial fallout of scientific progress must be shared by all nations, the role of UNESCO prevails over that of other organizations - except the United Nations - whose structure does not allow to have the same ambition or the same coherence. Past experience have shown that UNESCO could deal with questions which are more specifically in the domain of other organizations, if it is sure that it will succeed in its mission (for example, the Recommendation on the Status of Scientific Researchers of 20 November 1974).

In such a perspective, the questions of the protection of the human genome linked to medical research or to copyright should logically be raised by the international instrument, even in a subsidiary manner.

Furthermore, UNESCO has acquired a certain experience in the domain of bioethics, which it was interested in since the beginning of the 1970s. Therefore, in 1970, UNESCO organized in Madrid a symposium in collaboration with the Spanish Superior Council of Scientific Research and has since then multiplied efforts in the matter (symposiums, publications, thematic reports, etc.). In the Medium-Term Plan 1990-1995, a degree of maximum priority was given to actions by the Organization on the theme of the relationship between human rights and scientific progress.

## **VI. The Form and Content of the Instrument**

The elaboration of an international instrument for the protection of the human genome presents many difficulties because of its complexity, since we are touching on human rights, science, technology, ethical and deontological aspects, traditions, religious and regional aspects, beliefs and customs, on scientific freedom and progress.

It is the reason for which a general and flexible text must be drafted without affecting its importance and its efficiency.

The adoption of an international instrument for the protection of the human genome, at the end of the twentieth century, should be treated with prudence - and to be compatible with conscience since the question is extremely serious - and with the certainty that science will continue to advance as well as research in genetics. We can gather from that new dimensions will open for technology, gene therapy, genetic modifications and medicine. That is why there is a need to establish general principles and to assert the ineluctable respect for dignity, freedom and human rights, while remaining flexible in order not to interfere with scientific progress but respecting ethics and the responsibilities which come with it. Therefore it is necessary to conceive of a document which can remain timely and in accordance with progress and scientific changes in the future.

The task is difficult but we are facing of a challenge which obliges us to react.

## **VII. Equivalent Declarations and Their Place in International Law Today**

The adoption of a declaration as proposed requires determination with precision, in the actual state on the evolution of international law and the practice of States, of the value and of the significance of this type of instruments. Treaties and conventions - although this does not aim to diminish their importance - are only one of the sources possible of international law. This means, without prejudice to conventional sources, that there are other sources of international law, for example the declarations, which have a binding legal effect. This legal situation can therefore be used on the international level for the protection of the human genome.

Declarations, proclaimed by the supreme organ of an intergovernmental organization, especially in the United Nations system, if they are adopted under certain circumstances which have been specified in international practice, doctrine and jurisprudence, produce legal effect in becoming sources of international rights and obligations.

Can a declaration on the protection of the human genome have international legal effect concretely, aside from its political and ethical impact, and be able to serve as model for national legislation? Obviously yes, and this is today the case. Without prejudice to its perfecting and its implementation, it is necessary, in order to ensure its efficient application with responsibilities and adequate verification, to foresee the elaboration of a future convention.

## **VIII. The Content of the Declaration**

What are the contents of the proposed declaration and what is the preliminary outline which has been elaborated by the Legal Commission of the IBC? We must not forget that this is an instrument for the protection of the human genome and not a text concerning bioethics in general.

The 'Preliminary Draft' contains a preamble and six parts.

A preamble is essential for a declaration. It takes stock of precedents, quotes applicable principles and determines goals, all in an applicable legal and ethical context, in consideration of the present state of international law. This means that it takes into account scientific progress and the need to solve the problem in a standard-setting way with care, equilibrium, a sense of future, respect for freedom and moral conscience. It is therefore human dignity and the future of man and humankind that are in question.

The preamble, as for the Universal Declaration of Human Rights (by which we are inspired in a certain way) is part of the text, and it is a determining factor for the interpretation of all and of each of its parts, as established by the Vienna Convention on the Right of Treaties.

The first part of the document - which consists of four articles - considers the human genome as a common heritage of humanity. As such it should be the object of special protection.

The human genome, in since it constitutes the distinctive element specific to each individual as a component of his or her uniqueness, can be transmitted as heritage and thus comes under civil law with its responsibilities. On the other hand, the human genome, as part of the gene pool of the human species as a whole and which transcends individual genetic identities, is the common heritage of humanity and came under international law. The concept of 'common heritage of humanity' was in fact used in Article I, paragraph 3, of the Declaration of the Principles of International Cultural Co-operation of 4 November 1966, in referring to the diversity of the world's cultures.

Be that as it may, according to that formula, each human being is considered to be the 'depository' both of his or her genome and of the genome of the entire species, which in fact we share to an appreciable extent with other living species. Viewed in that light, the human genome, irrespective of its heritage status, can be said to create responsibilities towards oneself and specific obligations with the object of protecting the genetic diversity of humanity.

The protection of the human genome is to safeguard the integrity of the human species and, as such, the dignity of each of the members of the human family, in other words, each individual.

The genome is by nature evolutive and subject to mutations. The individual cannot be reduced to his or her genetic characteristics. Each human being has its own genetic identity which is unique. He has the right of respect for his or her dignity, whatever his or her genetic characteristics.

It is enough to point this out, in order to emphasize the human and ethical depth, the universal character, and the transcendence for the future of humanity and to assert the unique, special and full character of the human person, inseparable from the idea of dignity and rights.

The second part aims at providing a frame for the research and other interventions on the human genome in order to protect the human person.

On this subject, all discriminations based on genetic characteristics are forbidden. No research nor intervention on the human genome can be practised without the free and informed consent of the person in question. The confidentiality of genetic data should be protected.

The principle of responsibility - basis of indemnification - should be based on prejudices submitted by the individual as a result of research or intervention on the human genome.

The third part refers to the rights and obligations of researchers.

We try to establish in this part a balance between the rights and obligations of researchers in order to ensure intellectual and material conditions suitable for scientific progress, but in a context of social and moral discipline, of prudence and intellectual honesty.

The fourth part refers to rights and responsibilities - guaranteed by all States - based on the principle of solidarity regarding individuals, families and populations exposed to risks because of their genetic characteristics.

The fifth part refers to the international co-operation concerning the diffusion of knowledge in the matter of scientific co-operation, and more particularly between industrialized and developing countries.

The States are committed to promote scientific teaching, while taking into account social and ethical implications of human genetics.

The States are also committed to promote training and information, in relation with the growing awareness by the State's leaders of the progress in human genetics.

The last part refers to questions which concern the applications of the declaration.

It is inspired by the Universal Declaration of Human Rights and the Declaration on Principles of International Law concerning Friendly Relations and Co-operation among States (Resolutions 2625 (XXV)), which specify the obligations of States and individuals regarding the declaration, and the duty of States to encourage its application.

Finally, the verification of the application of the declaration is entrusted to the UNESCO International Bioethics Committee which has the competence to offer recommendations.

This part is no doubt essential. If the declaration is an international instrument which has political and moral consequences and, in certain conditions, legal obligations, it is necessary to establish a system - for the moment embryonic which will develop in time - for the verification of its application and to ensure its efficiency.

## **IX. The Subjects of Law and Obligations deriving from the Declaration**

What are the subjects of rights and obligations which emerge from this declaration?

For the instrument of the type of the declaration that we are to prepare, there may be a different answer if it were a convention.

The declaration, in view of its general character and aiming at the international community as a whole and each human being in particular, generates obligations and attributes rights to this community, to States which are part of it and to individuals, namely all human beings without exclusion and discrimination.

The reading of the draft of declaration permits finally to emphasize that certain principles, proclaimed in its first part, are at the basis of rights and obligations of all human beings.

The same applies to the second part which, moreover, for two cases (Art. 5 and 8), refers specially to candidates of recognized laws.

The third, fourth and fifth parts impose duties of different forms on the States.

Finally, the sixth part refers only to Member States of UNESCO, since it deal with a particular attribution which these latter made to the International Bioethics Committee and which concerns the verification and application of the declaration.

## **X. UNESCO and the Declaration**

To whom is this preliminary outline of a declaration destined?

The idea of this instrument was born at UNESCO and was elaborated and drafted within the Organization. The question is therefore deliberated by the competent constitutional structures in UNESCO. According to the established tradition, the declaration should then be adopted by the General Conference. This process, perfectly compatible with the present state of international law and the current practice of UNESCO, does not object to a parallel text to be eventually adopted by the General Assembly of the United Nations, nor that a convention on this theme be elaborated and adopted by UNESCO or the United Nations.

But UNESCO should not give up its pioneer work in this field today. That is why it should open the way to the adoption of a declaration which will be the first for the protection of the human genome on an international level.

# THIRD MEETING OF THE LEGAL COMMISSION OF THE IBC

(Paris, 19 September 1994)

## I. Introduction

The Chairperson of the International Bioethics Committee (IBC), Mrs Noëlle Lenoir, welcomed the members of the IBC's Legal Commission and the other participants. She reminded them that the task entrusted to UNESCO by the General Conference at its twenty-seventh session, held in November 1993, was 'to continue in 1994-1995 the preparation of an international instrument on the protection of the human genome' (27C/Res. 5.15).

In January 1994, the Legal Commission, chaired by H. Ex. Mr Héctor Gros Espiell, Vice-Chairperson of the IBC, had begun that important work, with the invaluable assistance of all the members of the IBC. Early in August 1994, a provisional version of the 'Preliminary outline of a declaration on the protection of the human genome' had been drawn up and communicated to all the members of the Legal Commission and to a number of experts. They had sent in their comments, which had been put to the Legal Commission at its present meeting. The Preliminary Outline dated 12 September<sup>(14)</sup> had taken into account the August 1994 consultation.

Lastly, Mrs Lenoir said that the purpose of the present meeting of the Legal Commission was to consider the preliminary outline and to make comments with a view to producing a revised version. The concern at present was to make improvements to the text and to examine its overall structure and the principles stated in it. In broad detail, the preliminary outline consisted of a preamble and an operative part, section one of which proclaimed 'the human genome, the common heritage of the human species'. Five further sections dealt with: research and operations connected with the human genome; the rights and obligations of researchers; duties and responsibilities towards others; international co-operation; and, implementation of the declaration.

## II. Presentation of the Report by the Chairman of the Legal Commission<sup>(15)</sup>

Mr Gros Espiell began by describing what had been done by the Bureau of the IBC and the Legal Commission since the establishment of the IBC in September 1993. He explained why the Legal Commission had proposed a declaration, to begin with, rather than a convention that would have binding normative force.

He went on to say what sources, in domestic law and in international law, had been drawn on by the Legal Commission in preparing the preliminary outline, based essentially on the principles of human dignity, integrity and freedom.

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14. See Annex II.

15. See pag. 41.

Lastly, he gave an explanation of each paragraph of the preliminary outline, defining the persons (individuals, researchers, medical doctors, etc.) and institutions concerned and the rights and obligations applicable to them on the basis of the above-mentioned principles.

### **III. Discussion of the Preliminary Outline**

The Legal Commission expressed its satisfaction at the preparation of the text submitted to it and thanked both the Chairperson of the IBC and the Chairman of the Legal Commission for adopting a consistent approach to the objectives pursued, implicit in the choice of a declaration, and for producing a concise text. In particular, the Commission emphasized the pioneering role of the declaration and the advantages offered by its flexibility, which enabled it to take into account the rapid pace of progress in genetics. It noted the balance struck between the necessary freedom of research, which contributed to the development of knowledge and human advancement, and the obligations and responsibilities attaching to it, having regard to its social, ethical and human implications.

The Chairperson of the Steering Committee on Bioethics (CDBI) of the Council of Europe said that the CDBI was considering drawing up an additional protocol on genetics, along the lines of the three protocols already prepared, which would be attached to the draft framework-convention on bioethics. She welcomed the forward-looking approach adopted by the IBC in respect of the human genome. It was essential that international law should tackle such issues from the beginning, rather than attempt *ex-post facto* harmonization of national laws already enacted.

#### **A. Preamble**

The Commission considered it desirable to include a reference to the United Nations Convention on the Prevention and Punishment of Genocide (1948) in the second preambular paragraph, which should also group existing instruments together by organization (United Nations, International Labour Office, UNESCO) instead of citing them chronologically.

The Commission also considered that the preliminary outline should prohibit the use of genetics and genetically-modified organisms for the purposes of war. To that end, the preamble could refer to the United Nations conventions on chemical and biological weapons.

#### **B. *The Human Genome, Common Heritage of the Human Species***

There was no doubt that the first operative section formed the cornerstone of the innovation introduced by the declaration. The various possible interpretations of the idea of heritage gave rise to discussions. It seemed advisable to keep it, however, as it could easily be transposed to science and technology. In addition, while it was acknowledged that the purpose of the expression 'common heritage of the human species' was to define the specific characteristics of that heritage, the general feeling was that it was more appropriate to refer to the broader concept of 'the common heritage of humanity', enshrined in international law.

On the one hand, the human genome, in so far as it was responsible for the distinctive features specific to each individual, as part of his or her uniqueness, could be transmitted as a heritage and thus came under civil law, with the responsibilities attaching to it. On the other hand, the human genome, as part of the gene pool of the human species as a whole, which transcended individual genetic identities, is the common heritage of humanity and came under international law. The concept of 'common heritage belonging to all mankind' was in fact used in Article I, paragraph 3, of the Declaration of the Principles of International Cultural Co-operation of 4 November 1966, in referring to the diversity of the world's cultures.

Be that as it may, according to that formula, each human being was considered to be the 'depository' both of his or her genome and of the genome of the entire species, which in fact we shared to an appreciable extent with other living species. Viewed in that light, the human genome, irrespective of its heritage status, could be said to create responsibilities towards oneself and specific obligations with the object of protecting the genetic diversity of humanity. The Commission considered in that connection that there was a need to look into the concept of 'future generations', enshrined in several international instruments, in particular in the twenty-third and last preambular paragraph of the United Nations Convention on Biological Diversity of 5 June 1992.



The first section perhaps also led on to the question of the non-commercialisation of the human genome. Nevertheless, advances in gene therapy and the considerable hopes it raised for the relief of human suffering and distress had to be taken into account. Once, genetic resources were being used, particularly for therapeutic purposes, the question arose whether partial gene sequences were or were not to be seen as a heritage and were or were not inalienable.

### **C. *Research and Operations Connected with the Human Genome and the Protection of the Human Being***

The discussion on this operative part of the declaration focused on the necessarily limited character, in practice, of the 'free and informed consent' that a person might give to genetic research or interventions. The conditions for the free and informed choice to which those words referred could only be relative. Recognition of the autonomy of individual will might well be a necessary condition, but was it a sufficient one? If there were limits to the conditions for making a free and informed choice, should safeguards be introduced in order to protect persons who, through lack of awareness or ignorance, might agree to expose themselves to research or operations not subject to any control?

Paragraph 6 highlighted in general the need to assert the principle of free and informed consent. Its purpose was not to define the scope of that principle or the ways in which it was to be applied.

The Commission considered it important to introduce the principle of compensation in paragraph 8, certainly for the first time in an international instrument. The principle is essential, since responsibility was the very root of ethics and has consequently to be affirmed. In reply to comments regarding the wording adopted, the Chairman of the Legal Commission said that the principle of compensation, as set out in paragraph 8, could not serve *a contrario sensu* to justify any injury that might be caused by research or through an operation.

### **D. *Rights and Obligations of Researchers***

This section of the preliminary outline fitted in directly with UNESCO's ethical mission. It was to be remembered that the General Conference of UNESCO, on 20 November 1974, adopted the Recommendation on the Status of Scientific Researchers, which dealt with the ethical aspects of scientific research while emphasizing its freedom.

This part of the future declaration should, of course, establish the principle of freedom of scientific research while seeking to ensure that research activities were regulated so as to guard against any undesirable trends. A consensus emerged within the Legal Commission on the need to recast paragraph 10 in order to avoid the present form of words which had too negative a connotation in relation to research activities.

Looking beyond the text under consideration, one member of the Legal Commission put forward the idea of an oath for researchers, along the lines of the Hippocratic Oath for medical doctors. He even suggested a form of words for possible communication by the IBC to any appropriate body<sup>(16)</sup>.

### **E. *Duties and Responsibilities towards Others***

The Commission considered that that section of the text faithfully reflected its previous discussions.

### **F. *International Co-operation***

The Commission wondered about the advisability of referring to the legal protection of the findings of genetic research. That was an ongoing debate (patent law; protection of genetic data banks; copyright; etc.) and the matter was also being dealt with by several other international organizations, in particular, in the United Nations system, by the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

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16. 'I undertake to pursue my research in order that knowledge and truth may benefit humanity and nature. I shall do everything in my power to ensure that science is not used against human beings or nature. I shall be guided only by truth, wisdom and my own conscience.'

The Legal Commission consequently expressed the wish that consultation should continue before proposing any form of words. In particular, it instructed the General Secretary of the IBC to organize appropriate meetings to define UNESCO's competence in this field and the systems that might be explored to that end<sup>(17)</sup>.

### **G. Implementation of the Declaration**

The Commission considered that the task that might be entrusted to the IBC, or to a subsidiary body, in implementing and following up the declaration would make it possible to evaluate the provisions laid down in the light of advances in genetics and its applications. In addition, a periodic evaluation of that sort would facilitate the preparation of a future convention.

The Commission also considered that that part of the text should, in one of its provisions, lay down the obligations of States, which should then be guided by the principles of the declaration when adopting domestic measures.

## **IV. Conclusions**

In conclusion, the Chairperson of the IBC thanked all the participants for a constructive discussion and for all the suggestions made by them to give more substance to the proposed text. She pointed out that the whole of the preliminary outline was underpinned by human rights, which were universally recognized and proclaimed by the international community. Stressing the pragmatic and gradual approach adopted from the outset by the IBC, she went on to say that the text should constantly take into account the present state of knowledge in genetics and the real issues involved.

On the basis of the deliberations of the Legal Commission of the IBC at its third meeting, a revised version of the declaration<sup>(18)</sup> would be drawn up. The revised version together with a questionnaire would be sent to a hundred or so institutions and specialists, who would be asked for their comments and possible suggestions for amendments.

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17. An 'International Workshop on Legal Systems for the Protection of the Results Genetics Research' was organized by UNESCO, on 30 and 31 January 1995, with the participation of several members of the Legal Commission of the IBC and experts in patent law and copyright law (Ref. UNESCO/CLT/BCR/CIP.BIO/3).

18. See Annexe III.

# **FOURTH MEETING OF THE LEGAL COMMISSION OF THE IBC**

(Paris, 27 April 1994)

## **I. Introduction**

The aim of the fourth meeting of the UNESCO International Bioethics Committee's Legal Commission was to consider the 7 March 1995 version of the Outline of a declaration on the protection of the human genome<sup>(19)</sup>, to look at the initial comments made by the organizations concerned and to decide on the way in which the international consultation on the outline would be carried out.

Several other working documents in addition to the 7 March 1995 Outline were prepared for the fourth meeting: a questionnaire to focus the international consultation and a presentation of the outline to explain to readers the objects of the future declaration, the concepts used in it and the connection between its various parts.

A further document provided was the report of the 'International Workshop on Legal Systems for Protection of the Results of Genetics Research', held by UNESCO on 30 and 31 January 1995.

The Chairperson of the IBC reported on the substantial comments made on a previous version of the outline (dated 20 December 1994)<sup>(20)</sup> by several members of the IBC, in particular Mrs Bartha Maria Knoppers, Mr Sidney Altman and Mr Gonzalo Figueroa Yañez.

## **II. Statement by the Chairman of the Legal Commission**

In presenting the outline, H. Ex. Mr Héctor Gros Espiell, Chairman of the Legal Commission, concentrated on the form of the planned international instrument, its innovative features in terms of international law and the multidisciplinary nature of the consultation that has begun between intergovernmental and international, regional and national non-governmental organizations.

In the first place, a declaration is the form best suited to an international instrument on the protection of the human genome. It allows the document to be more flexible, whilst conferring a certain legal force upon its provisions. The example of the Universal Declaration of Human Rights demonstrates the potential effectiveness of a declaration. The convention form might not sit easily with the nature of the field in question. Genetic research is advancing rapidly and would not fit into too rigid a framework, which would consequently be out of step with scientific and social reality.

Regarding implementation of the future declaration - rarely provided for as such in an instrument that is not conventional - Section F of the outline proposes that the IBC be asked to implement it, thus providing a monitoring mechanism, and that to that end it be given the power to make recommendations and give advice.

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19. See Annex IV.

20. See Annex III.

Secondly, the outline declaration declares the human genome to be 'the common heritage of humanity'. While the concept of common heritage of humanity has gradually spread throughout international law - in particular in the early 1960s in the law of the sea - this will be the first time it has been extended to the specific nature of humankind itself, which is at the same time the most personal part of a human being, namely the genome. 'Humanity' here does not have a philosophical meaning. It refers to a legally applicable concept, humanity being regarded as a subject of international law, with rights and responsibilities towards itself and towards future generations.

The concept of 'common heritage of humanity' was initially devised in international law in the first half of the nineteenth century by Andrés Bello and developed by de La Pradelle in the context of the law of the sea, and it has concerned spaces outside human beings such as the sea bed (in the United Nations Convention on the Law of the Sea) and the moon and celestial bodies (in the Agreement Governing the Activities of States on the Moon and Other Celestial Bodies), and humankind's symbolic spaces, such as culture (in UNESCO's 1966 Declaration of the Principles of International Cultural Co-operation, Art. 1, par. 3). It should be pointed out that the Constitution of UNESCO refers to 'the conservation and protection of the world's inheritance of books, works of art and monuments of history and science' (Art. 1, par. 2, sub-par. c).

The outline declaration, by proclaiming the human genome, common heritage of humanity, aims to stress that humankind has a particular responsibility with regard to the human genome as one of the elements that make up the identity of each of us and indeed the identity of humankind itself. The concept therefore applies to all the expressions of the human genome - past, present and future -, which are the source of diversity and of the potential for genetic evolution. The human genome, then, could be considered to be in some respects an intangible good (see Chapter 2 of the Report of the International Workshop on Legal Systems for the Protection of the Results of Genetics Research).

Lastly, the future declaration must, and with good reason, be the subject of extensive international consultation involving scientists, philosophers, legal experts and other specialists in the social and human sciences. Although declarations adopted within the United Nations system are drafted by the representatives of governments before being adopted by conferences of States - as was for example the Universal Declaration of Human Rights, proclaimed by a resolution of the United Nations General Assembly on 10 December 1948 - in this case the fundamentally transdisciplinary nature of the future declaration on the protection of the human genome requires a more complex drafting procedure more likely to ensure its success.

### **III. Comments by the International Federation of Philosophical Societies**

On behalf of the Bioethics Commission of the International Federation of Philosophical Societies (FISP), Mr Gilbert Hottois, member of the FISP Steering Committee and Co-ordinator of the Bioethics Commission, introduced its comments on the December 1994 version of the outline of a declaration on the protection of the human genome.

The FISP Bioethics Commission first of all acknowledged the quality of the outline, which was destined to become an ethical reference instrument once it had been adopted. The outline's six sections covered broadly the various aspects of protection of the human genome, even though specific issues such as germline gene therapy and pre-implantation diagnosis were not addressed in it.

Speaking generally, the declaration that the human genome is common heritage of humanity was not immediately understandable. Moreover the outline seemed to oscillate between protecting the rights of the individual in relation to genetics and protecting the human genome, which was seen as a sort of essence of human being, a concept hard to defend, since humans share a very large part of their genome with other living species. The idea was put forward of calling the future instrument: declaration on the protection of individuals in relation to genetics.

Lastly, there were more specific remarks on certain passages of the outline. For instance, paragraph I made safeguarding the integrity of the human species the purpose of protecting the human genome. This surely did not refer to the inviolability of genetic material, since that was ruled out by the document's assertion that the genome was subject to mutations and acknowledgement that operations on the human genome were possible provided [sic] they had a 'scientific, therapeutic or diagnostic purpose' (par. 8).

Paragraph 3, by stating in principle that 'each human being possesses a specific genetic identity', seemed to reduce identity to its genetic dimension alone, whereas an individual's identity was to say the least complex, included cultural and educational components and expressed his or her history.

The wording of paragraph 7 would benefit from qualification, because circumstances might on occasion justify 'discrimination on the basis of ... genetic characteristics'. In this case it might be appropriate to qualify discrimination by adding 'unfair'.

Although paragraph 8 stated that 'prior, free and informed consent' must be obtained in the case of an operation on a person's genome, Mr Hottos nevertheless stressed the absolute care that must be taken in such cases.

The exceptions hedging paragraph 9, on the confidentiality of genetic data on an individual, robbed it, in his opinion, of some of its substance and scope.

Finally, the right to compensation for injuries sustained as a result of an operation on a person's genome was far too general as worded in paragraph 10, especially as it did not distinguish between levels of responsibility (such as responsibility for accidental injury as opposed to injury due to negligence).

#### **IV. General Discussion**

The discussion, which covered the introductory statement by the Chairman of the Legal Commission and the presentation of the comments of the FISP Bioethics Commission, highlighted the value of a debate between representatives of various disciplines and different cultural sensitivities. The language used in the outline should probably be scrutinised with an eye to preventing ambiguity arising from multiple semantic connotations. As it is first and foremost a legal document, however, it must have the rigour and terminological clarity of such a document and avoid all unnecessary prolixity.

As for genetic reductionism, the outline clearly refutes that by stressing the importance of environmental and cultural factors in making up the personality of each individual.

Regarding discrimination, that is in itself an infringement of the right that forms the basis of equality between men and women. On the other hand, the principle of non-discrimination does not exclude differentiation that is justified by the specific circumstances of a given situation. For instance, the law may stipulate that an airline pilot with a genetic susceptibility to cardiovascular disease, especially heart attack, should not - because of the potential risk to the public - fly airliners.

The fact that the scope of the right to compensation is not specified in the outline is deliberate, since it must be left to the national legislature or judicial precedent to determine its limits and the conditions of its application (as regards negligence and risk) in accordance with the legal system of the country in question. Even so, it is important to state the principle of the right to compensation for injuries sustained as a result of an operation on a person's genome, such right arising from the ethics of responsibility.

With regard to the common heritage of humanity, of course this concept was originally intended to limit the excesses of sovereignty over spaces of communal interest. The use of the concept of common heritage of humanity in the declaration comes as an extension of the growing awareness of the shared destiny of humankind and the responsibilities that result from it, whether they touch on climate change, pollution, demographic growth or even the potential use of scientific research for repression or war. The concept is becoming an element in the protection of the collective interests of humankind against possible infringements of human dignity affecting its common future. It is based moreover on the current notion of sovereignty, which is compatible with international law. Bringing the notion of common heritage into play in the declaration is an attempt to secure the broadest possible protection of the human genome against damage that might endanger the very survival of humankind. In addition, the notion of heritage covers the knowledge accumulated by men and women about themselves as a source of potential for the progress of humankind.

## **V. Organization of the International Consultation**

At the initial stage the members of the IBC, the United Nations (in particular the Sub-Commission on Prevention of Discrimination and Protection of Minorities), the Specialized Agencies of the United Nations system (particularly the World Health Organization, the International Labour Organization, the Food and Agriculture Organization and the World Intellectual Property Organization), regional intergovernmental organizations (such as the Council of Europe, the Organization of American States, the Pan-American Health Organization, the European Commission, the Organization of African Unity and the Arab League Educational, Scientific and Cultural Organization), non-governmental organizations (in particular the Council for International Organizations of Medical Sciences, the International Council for Science, the International Social Science Council, the International Council for Philosophy and Humanistic Studies, the World Federation of Scientific Workers and the Human Genome Organization), academies of science, university law faculties and national ethics committees will be consulted on the basis of the questionnaire between May and July.

A summary of the replies to the questionnaire and, if need be, an update of the outline will be made available to the IBC members in September 1995.

At the second stage, after the twenty-eighth session of the General Conference (October-November 1995), States will be consulted in accordance with existing procedures for the adoption by the General Conference of an international instrument, in this case the declaration on the protection of the human genome.

## **VI. Conclusions**

The Chairman of the Legal Commission summed up the conclusions to be drawn from the fourth meeting by reiterating the work to be done by September 1995. Firstly, the consultation file on the 7 March 1995 Outline would be sent to all IBC members, initially in French and English and subsequently in Spanish for those who so wished. IBC members were invited, ideally in collaboration with the National Commission for UNESCO of their country - whose address would be sent to them - to have the outline scrutinised and commented upon in their respective institutions.

Secondly, the programme for the third session of the IBC (27-29 September 1995) should allow for a debate on the outline, which would be updated in two stages: at the very beginning of the third session and towards the end of its proceedings. This two-stage examination would facilitate discussion between the members of the IBC.

The Secretariat should prepare two separate documents for the third session. The first should present general observations on the outline (choice of formulation, structure, form and so on) and also a detailed article-by-article analysis (for example with quotations from international reference instruments) and a summary of the comments made by the members of the Legal Commission.

The second document should contain a summary of the replies to the questionnaire. It would also be in two parts and would first of all present the general observations made and then the specific remarks, article by article.

After thanking all the participants, the Chairperson of the IBC said that the expanded meeting of the Bureau on 28 April 1994 would fill in the details regarding the programme and the organization of the third session of the IBC.

# **FIFTH MEETING OF THE LEGAL COMMISSION OF THE IBC**

(Paris, 25 September 1995)

## **I. Introduction**

The purpose of the fifth meeting of the Legal Commission of the IBC was to consider the initial results of the international consultation on the outline of a declaration on the protection of the human genome<sup>(21)</sup> and to examine how the main comments received could be followed up.

To that end, the file handed to each participant contained the following documents: material on the consultation on the outline, the Report of the fourth meeting of the Legal Commission of the IBC, a text by the Chairman of the Legal Commission on the concept of common heritage of humanity, the comments of three members of the IBC on the outline of a declaration, and the Report of the Director-General on the possibility of drawing up an international instrument on the protection of the human genome (Document 28 C/38).

H. Ex. Mr Héctor Gros Espiell, the Chairman of the Legal Commission, pointed out that in view of the wealth and diversity of contributions received the UNESCO Secretariat had grouped the comments according to subject matter in order to facilitate their analysis.

## **II. Analysis of the Initial Results of the Consultation Carried out on the Outline of a Declaration**

In his introductory remarks, the Chairman of the Legal Commission stressed the unquestionable quality and substance of the comments which had been sent in both by members of the scientific community and by legal experts, members of academies and many other institutions. The comments thus presented were, in his opinion, both relevant and stimulating for the reflection of the IBC members.

An initial issue, already brought up in the comments made by the representative of the International Federation of Philosophical Societies to the Legal Commission on 27 April 1995, was raised by the President. Should it not be more clearly underlined that the essential purpose of the future declaration was to guarantee respect for human dignity and human rights with regard to the human genome? The President proposed that the title of the declaration be modified to that effect to take account of this concern.

With regard to the qualification of the human genome as common heritage of humanity, the President considered that the objections raised stemmed perhaps from an inadequate understanding of this legal concept. The term did not in fact apply only to material assets that could be exploited

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21. See Annex IV.

economically. Nowadays, international law made use of this term in the field of culture, for example in the UNESCO Constitution, and in human rights. In the latter case, the Preamble to the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 referred to the 'common heritage of political traditions, ideals, freedom and the rule of law'. The term 'common heritage of humanity', which was attributed to the human genome, should therefore be maintained in the declaration in view of the need to guarantee respect for human dignity and human rights and the need for a balance between the protection of individual rights and the common interest of humanity. The rights of the individual and the common interest of humanity were indivisible in this context and mutually reinforced one another. It was proposed that Article 1 be expanded in order to express more clearly in the declaration what was implied by the use of the concept of common heritage of humanity.

Several comments reflected the wish that a definition of the human genome should be given in the declaration. Although it was standard practice to define the terms used in a legal instrument, it would be preferable to refrain from doing so in the declaration in view of the risk of scientific definitions becoming obsolete due to the rapidity with which new discoveries were made.

The question of liability regarding interventions affecting the genome, which was addressed in particular in Article 10, raised a number of issues. That article, which laid down the principle of civil, rather than criminal, liability, asserted a general principle of liability without going into the details of how it was to be implemented.

In further pursuit of the matter, the requirement of the prior, free and informed consent of every person undergoing an intervention affecting his or her genome was raised. Article 8, which was intended to provide a guarantee in that context, did not take account of the difficulty of obtaining such consent and in particular of all the factors, especially cultural factors, which could impair the validity of the consent given.

Lastly, the Chairman of the Legal Commission did not consider it appropriate to take up the proposal aimed at prohibiting interventions affecting germline cells, despite the fact that he was of the opinion that such interventions should not be allowed. The purpose of the declaration was to assert principles intended as a guide for the action of the officers and professionals concerned. It was not designed to regulate scientific or medical practice.

### **III. General Debate**

#### ***The Human Genome, Common Heritage of Humanity***

With regard to the qualification of the human genome as the common heritage of humanity, it was suggested that the declaration should emphasize the fact that before being part of the common heritage the human genome was first and foremost the property of the individual. The reference in Article 2 to the evolutive nature of the genome should be offset by a reference to the need to protect the genetic identity of the individual.

Mrs Noëlle Lenoir, Chairperson of the IBC, pointed out that it would be difficult to state in a declaration that the individual was the 'owner' of his or her genome, since that would run counter to the legislation of certain countries, including France, which did not recognize ownership of the human body. It would be desirable, on the other hand, to assert more firmly that every individual had a genetic identity and that no operation affecting that identity might be carried out against the wishes of the person concerned.

Since the patentability of the genome was not dealt with in the declaration, should there be a reference in the preamble to the international instruments concerning the protection of intellectual property rights? Similarly, should a new article be added to the declaration making provision for the prohibition of all forms of appropriation or marketing of the results of genome research? Any prohibition of the possibility of patenting the results of research in the field of human genetics would have a significant impact on research itself, since prohibiting all possibility of gaining commercial benefits would be liable to discourage research work.



It would be difficult to address the important and complex issue of the patentability of human genetic sequences in the UNESCO context alone, particularly in view of the economic interests at stake. The need for a balance between the imperative of free access to the results of genome research and the investment essential for developing that research must be borne in mind. Reflection on the conditions for protecting research results should be pursued in greater depth. It would seem difficult at all events to advance much further on this subject within the context of a general document such as the declaration on the human genome.

The Chairperson of the IBC stated that the concept of common heritage of humanity was not incompatible with the prospect of the patentability of the human genome. The common heritage concept simply aimed to assert the principle of freedom of access to the results of genome research. She was of the opinion that UNESCO could not go any further in the declaration with regard to the question of patentability, in view of the many interests at stake. She proposed, on the other hand, that in-depth examination of the matter be continued in the context of the IBC's work on ethics and genetic data banks.

### ***Interventions Affecting the Human Genome***

A debate developed on the principle of liability in the event of injury sustained as the result of an intervention affecting a person's genome. It was considered preferable to replace the right to reparation by the right to compensation and to state in the relevant article that it was impossible for children to sue their parents for damages. Care should be taken not to assert 'genetic rights' as a result of which children would be able to take legal action against their parents for genetic injury. With regard to the question of causality, if, in order to establish liability, the person concerned must be able to provide proof of a causal link between the injury he/she claimed to have suffered and an intervention, it would seem desirable that the onus of proof should not be on the victim. As to the question whether Article 10 made it possible to render the persons performing the intervention liable, it was pointed out that by law liability could be incurred on grounds of negligence or risk. A more open formulation was suggested with regard to the right to compensation, since, while the right to reparation could result in compensation, it was not limited to that.

The Chairperson of the IBC considered that Article 10 set forth a major innovatory principle, which could be exercised in a universal context. Specifically, it laid down a principle whose purpose was to ensure the protection of individuals in the event of an intervention affecting their genome, particularly in the case of relocated experiments carried out in the countries of the South. The wording of the article should be revised to that effect.

The participants were reminded of the conclusions regarding free and informed consent which had been reached at the meeting in Santiago, Chile, organized by Professor Gonzalo Figueroa Yañez. It was stressed that it was desirable that the declaration exclude any possibility of performing an operation affecting a person's genome unless for scientific, therapeutic or diagnostic purposes. A further condition for performing an operation on a person's genome must therefore be added to Article 8: that of the assessment of the risks and advantages for the person concerned. Furthermore, despite the possible drawbacks of the excessive protection of persons who were *de jure* or *de facto* incapable, the possibility of carrying out research from which they might benefit must be left open.

It was pointed out that the condition of the free and informed consent of the individual concerned was not always appropriate in situations where the group (family, community, etc.) played a predominant role. Article 8 should be reworded to that effect in view of the importance of this issue.

### ***Rights and Obligations of Researchers***

It was suggested with regard to the regulation of genetic research that the declaration be confined to entrusting this responsibility to the researchers themselves, urging them to comply with special obligations of meticulousness, caution, etc..

The Chairperson of the IBC pointed out that the declaration contained another article which invited States to regulate genetic research. She stressed that it would be desirable for the declaration to contain a new article recommending that States set up independent ethics committees, which would have the effect of stimulating public debate on the issue of the applications of genetics. This draft article was approved, subject to certain clarifications that might be added, such as the independence of

these committees, the multidisciplinary and pluralistic nature of their composition, their means of action, etc.. An effort should be made to take advantage of existing structures in this area: ethics committees functioning at the national or local level, bodies set up on the initiative of governments or private entities.

### ***Standardization of Terminology***

With regard to the terminology used in the declaration, attention was drawn to the advisability of certain formulas such as 'States shall undertake'. It was stressed that it was standard practice in international law to use wording in declarations that was binding upon States. The purpose was not to create legal constraints, but to commit States morally.

The terminology of the declaration, in which the terms 'person', 'human being', 'individual' or 'no one', 'everyone', and so on were used, should be standardized, except in cases where there was a logical reason for such diversity. The matter would be taken up again at the sixth meeting of the Legal Commission.

## **IV. Conclusion**

At the conclusion of the discussion, Mr Mohammed Bedjaoui said that he wished to stress that, in his opinion, the draft declaration on the human genome was a text of great quality, even though there was still room for improvement. He underlined its two strong points: the concept of the human genome as the common heritage of humanity and the statement of the rights and obligations of researchers.

The Chairman of the Legal Commission thanked the participants and stated that a new draft reflecting their comments and any new elements arising as a result of public debate would be presented at the sixth meeting of the Legal Commission, which was scheduled for 25 January 1996.

# **SIXTH MEETING OF THE LEGAL COMMISSION OF THE IBC**

(Paris, 25 January 1996)

## **I. Introduction**

The purpose of the sixth meeting of the Legal Commission of the International Bioethics Committee of UNESCO (IBC), held in Paris on 25 January 1996, was to finalize the revised version of a 'Preliminary Draft of an International Declaration on the Human Genome in Relation to the Protection of Human Rights'<sup>(22)</sup> by examining it article by article.

The file handed to each participant contained a provisional version of the Preliminary Draft in question, drawn up on the basis of the observations on the text of 7 March 1995 gathered during the international consultation and the debate of the Third Session of the IBC, as well as a comment recently forwarded by an international non-governmental organization. The file also contained a summary of the debate on bioethics at the twenty-eighth session of the General Conference and a memorandum prepared for the members of the Legal Commission.

The General Secretary of the IBC opened the meeting by stressing the very favourable reception the work of the Committee had received at the twenty-eighth session of the General Conference. 28 C/Resolution 2.2 inviting the Director-General to draw up a preliminary draft declaration on the bases proposed by the IBC was unanimously adopted. Furthermore, the General Conference considered that the human genome was part of the common heritage of humanity. 28 C/Resolution 0.12, entitled 'Medium-Term Strategy for 1996-2001', reaffirmed 'the urgent need to strengthen the moral solidarity of mankind in order to safeguard its common heritage - natural and cultural, tangible and intangible, intellectual and genetic'.

Before beginning the article-by-article discussion, the participants took note of the draft summary of the findings of the international consultation on UNESCO's outline declaration on the human genome<sup>(23)</sup>.

## **II. Summary of the Findings of the International Consultation on the UNESCO's Outline Declaration on the Human Genome**

The informal international consultation on the Outline declaration launched jointly by the Chairperson of the IBC and the Chairman of the Legal Commission produced many of highly relevant observations. In addition to those presented at the Third Session of the IBC, they form the basis of the new version of the declaration.

The final summary of the observations gathered confirmed the initial findings presented at the fifth meeting of the Legal Commission of 25 September 1995. The essential matters of concern to the commentators focused on a number of major themes, namely, the purpose and goals of the declaration and the scope of the notion of common heritage of humanity.

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22. See Annex V.

23. See page 67.

The essential purpose of the declaration is to protect human dignity and human rights, not to protect the human genome, which meant first that the title had to be modified. The value of a person is independent of his or her genetic characteristics. Whatever his or her biological 'strengths' or 'weaknesses', every individual is entitled to the protection of his or her dignity and rights. It did not seem possible to adopt the idea of seeking to ensure the inviolability of the human genome. Genetic mutations were likely to be beneficial, although it had to be stressed that, in the present state of scientific knowledge, germline therapy was not admissible.

Did describing the human genome as common heritage of humanity imply prohibiting the patenting of human genes? It was undeniable that the notion tended to emphasize the fact that knowledge about the human genome should not remain the privilege of the few and should benefit humanity as a whole. In particular, it did not in itself exclude putting into practice the principle of free access to the findings of scientific knowledge on the genome, if necessary, provided that intellectual property rights were respected. The momentum of research on the genome depended on that. However, as had already been emphasized several times, UNESCO was in any case not competent to make a unilateral ruling on this question, which concerned above all the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).

Comments were made on a few other points of the declaration, in particular the need to regulate more strictly interventions affecting the genome to prevent any eugenic abuse. In response to this observation, the new preliminary draft declaration provides that such interventions may be undertaken only for scientific, therapeutic or diagnostic purposes, in order to avoid the development of practices such as choice of sex of the embryo.

The proposal already approved by the Third Session of the IBC to subject any intervention on a person's genome to prior, rigorous assessment should also be recalled, as should the proposal to substitute for the 'right to compensation' in case of injury to a person's genome, following an intervention, a right 'to just reparation', a more flexible legal concept since it makes no assumptions concerning the form which such reparation might take.

It should be noted that some commentators recommended explicitly prohibiting the use of genetics for military purposes and called for the institution of an international system of control for genetics research which would be able to guarantee that such a prohibition was respected.

While some expressed the wish that the concept of human genome be defined in the preliminary draft, the Chairman of the Legal Commission took the view that a definition would have more disadvantages than advantages, while its absence would in no way prevent perfectly clear principles from being affirmed.

The Chairman of the Legal Commission concluded by inviting the participants to submit written comments about the various essential themes of the future declaration, a list of which was proposed in an information note for the Members of the Legal Commission (human dignity, non-discrimination, the human genome in international law, freedom of research, the responsibility of scientists, individual consent, confidentiality of genetic data, risk and duty to compensate, follow-up and application of the future declaration).

### **III. Article by Article Discussion**

#### **A. *Title of the Future Declaration***

Discussion began with the title proposed for the future declaration, the wording of which did not satisfy participants. In relation to a document seeking to protect the genetic identity of the whole human race, the term 'universal' declaration was considered more appropriate than 'international' declaration.

Some speakers wondered if it would not be preferable to speak of 'human genes' or 'human genetics', since we do not know exactly what the human genome is. After discussion, although the term 'human genome' does not have a very precise scientific definition, it was decided to keep the reference to this concept. Because everyone was already referring to the 'declaration on the human genome', as the Chairperson of the IBC stressed, it made it possible to highlight the responsibility of the scientists who had initiated the research programme which they themselves called the 'Human Genome Project'.

Furthermore, a consensus emerged as to the need to refer to human rights in the declaration's title.

The declaration will therefore be called '*Universal Declaration on the Human Genome and Human Rights*'.

## **B. Preamble**

### First Preambular Paragraph

Improvements of a formal nature were proposed and approved.

### Third Preambular Paragraph

The exact titles and dates of adoption of the conventions cited should be specified.

### Introduction of a New Preambular Paragraph

As the declaration referred to the United Nations Convention on Biological Diversity, in order to clarify the reference it would be necessary to insert in the preamble a paragraph about human genetic diversity, as it might otherwise be inferred that the stipulations of that Convention were applicable to human genetic resources.

In that connection, it was considered that, while a paragraph about human biological diversity should be included, it was difficult to claim that genetic diversity was a factor in the progress of humanity and that it reflected the influence of the environment. The participants agreed on the principle of a new preambular paragraph, the wording of which should note the genetic diversity of humanity and state that it should not give rise to any interpretation of a social or political nature.

### Fourth Preambular Paragraph

The question arose as to whether it was preferable to speak of progress in biology and genetics, or simply of genetics, or, alternatively, of biology. Genetics is, of course, a branch of biology. The Chairperson of the IBC said that the dual reference to biology and genetics sought to extend to life as a whole the desire to promote the beneficial development of scientific progress, the premises of which could be inferred from the increase in xenografts, for example.

### Fifth Preambular Paragraph

#### *Sub-paragraph (a)*

The reference to the 'well-being of peoples' was not useful, and the participants considered it preferable, if the intention was to include both the individual and the collective aspects of well-being, to speak of the 'well-being of humankind as a whole'. Should the prospects for improving health also be mentioned in that paragraph, as the World Health Organization (WHO) wished? Although the concept of well-being in WHO's Constitution covered that of health, as it is inevitable that, the beneficial effects of research on the human genome will broadly affect the field of health, it was decided to accept WHO's proposal.

#### *Sub-paragraph (b)*

It was decided to state that the aim is to prevent eugenic practice that runs counter to human dignity and human rights, and not dignity or rights.

## **C. Operative Part**

### Article 1

Some members of the Commission were uncertain about the notion of common heritage of humanity, as States were liable to use it to regulate the right of individuals to procreate. The Chairman of the Legal Commission observed that UNESCO's General Conference had already approved the concept of the human genome as part of the common heritage of humanity in 28 C/Resolution 0.12 (See Section I).

After a detailed discussion, the participants unanimously agreed to divide in two Article 1, whose last sentence concerning the goals of the protection to be promoted would become a new article transferred to the following section concerning research on the human genome. The first part of the future declaration would deal only with the essence of the human genome, and Article 1 would simply stipulate that it was a fundamental component of the common heritage of humanity.

### Article 2

In order to make this article more readable, the participants decided to divide it into three subparagraphs (a), (b) and (c).

### Article 3

It was decided to eliminate the reference to the state of health of each family.

### Article 4

The participants thought it more judicious to merge Articles 4 and 5 into a single article, reversing the order.

### Article 5

See above, Article 4.

### Article 7

The participants discussed this article at length, first in relation to the question of abortion on therapeutic grounds that the article in question did not seek to condemn, then the issue of justified discrimination and, in that connection, the possibility of 'positive' discrimination, prohibition of which should not be implied either.

Several members of the Commission wondered whether introducing the word 'person' at the beginning of the article was not likely to spark a debate as to whether or not the embryo was a person. Substituting the term 'person' for the term 'no one' that had been used previously, might in fact raise more questions than it answered. It was therefore decided to reinstate the term 'no one' as being more forceful, and to clarify the scope of the article by detailed explanations in the report presenting the declaration, which would be prepared.

In order to limit the scope of Article 7 to unjustified and therefore reprehensible discrimination, the participants agreed to state that only discrimination that aimed or had the effect of injuring the recognition of human dignity or human rights was prohibited. This wording would, for example, allow restrictions as to the employment of persons exposed to special genetic risks incompatible with the conditions of employment in question, in order to protect their health.

### Article 8

First it was decided to place this article at the beginning of the section devoted to interventions affecting the human genome.

Discussion then turned to the scope of the term '*intervention*', translated into English as 'operation'. Was the declaration to concern only interventions that modified the genome, or also studies on the genome as well as genetic tests? If the aim was to protect the individual in the context of genetic tests and therefore make such tests subject to a consent procedure, it was difficult to settle for a limited conception. On the other hand, the use of biological samples taken from persons, on the basis of data made anonymous for the purposes of epidemiological studies, should not be regarded as an intervention on an individual's genome. In any case, it was decided to avoid the use of the term 'operation' in the English version, as it was unsuitable as a translation of the French term '*intervention*'.

The question was raised of genetic finger-printing that might be ordered as part of judicial proceedings - for example, to establish filiation. Did the present wording not prohibit the possibility, as the aim of genetic finger-printing was neither scientific, nor therapeutic nor diagnostic? Similarly, did not the wording of the article also exclude research an individual might wish to be carried out as

regards his or her filiation, with no medical grounds? Prudence required that grounds for interventions affecting the human genome should not be too limited, insofar as it was doubtless difficult to imagine now all the future implications of research on the genome. In order to resolve those problems, it was suggested that mention should no longer be made of the purposes of interventions affecting the genome, but that such interventions should be made subject to the consent of the person concerned, prior assessment and perhaps the condition that the interventions respected that person's dignity and rights.

In order to take into account all those comments, in the end it was decided to redraft the article.

#### Article 10

One member of the commission raised the issue of the right to just reparation envisaged in the event of injury. At present, at least in the United States of America, a person on whom experimental treatment was attempted as a last resort, with his or her consent, had no right to reparation in the event of injury resulting from the intervention. Should a different rule be drawn up for interventions of a genetic nature?

The Chairperson of the IBC pointed out that this article, which was innovatory in an instrument of international law, sought above all to provide all individuals with rights in relation to high-risk experimentation: the promoters of such research (particularly industries) might thus be liable for injury, even if the experimentation was conducted in countries which had no protective legislation on the matter.

The participants wondered whether the right to reparation could be exercised even in the absence of fault. It was emphasized that, if such was the case, a brake might be put on medical research in genetics. Conversely, others considered that the priority should be to make researchers aware of their responsibilities when their experimentation presented serious risks. It was proposed that the article should be qualified by stating that every individual has the right 'in principle' to just reparation.

#### Article 15

It was agreed to modify Article 15 by stating that States would foster the dissemination of scientific knowledge 'with due regard for democratic principles' in order to limit the risks of their being used for purposes contrary to those principles.

#### Titles of the Various Sections

Lastly, in addition to the above-mentioned decisions, it was also decided to entitle the various sections of the future declaration as follows:

- A. The Human Genome;
- B. Research on the Human Genome;
- C. Interventions Affecting the Human Genome;
- D. Rights and Obligations of Researchers;
- E. Duties and Responsibilities towards Others;
- F. International Co-operation;
- G. Implementation of the Declaration.

## **IV. Conclusion**

The Chairperson of the IBC indicated that the preliminary draft declaration would be redrafted on the basis of the Legal Commission's comments and those that might be sent in writing. The new document<sup>(24)</sup> would be presented to the IBC for approval at its fourth session in October 1996. With regard to the translation problems that had been raised, any suggestions likely to improve the English version would be welcome.

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24. The provisional version of the preliminary draft of 29 January 1996 in Annex VI was revised by the President of the IBC and the Chairman of the Legal Commission during a working party meeting.

She said that the Legal Commission would hold a further meeting on the eve of the fourth session of the IBC, the two themes of which would be:

- a) Access to experimental treatment and protection of the human rights;
- b) Food, plant biotechnology and ethics.

She then thanked all the members of the Legal Commission for their valuable contributions, and announced that, when the preliminary draft declaration had been approved by the IBC, the UNESCO Secretariat would prepare a brochure presenting it that would bring together the most important texts which had played a part in its drafting.



# INTERNATIONAL CONSULTATION ON THE OUTLINE OF A UNESCO DECLARATION ON THE HUMAN GENOME

(Paris, 5 April 1996)

## Introduction

Between May 1995 and January 1996, the International Bioethics Committee of UNESCO (IBC) undertook a broad international consultation on the 'Revised Outline of a Declaration on the Protection of the Human Genome' of 7 March 1995<sup>(25)</sup>.

A questionnaire, accompanied by an explanatory text and the revised outline, prepared for the purpose of the consultation, was sent to more than 300 experts and personalities and to international and national bodies, including the United Nations and its Specialized Agencies, intergovernmental and non-governmental organizations, academies of sciences, universities and ethics committees<sup>(26)</sup>.

The results of the consultation are contained in the present document. The first part presents the replies to the questionnaire; the second part examines the observations and suggestions which were made on the text of the revised outline.

The 'Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights' of 4 March 1996<sup>(27)</sup> takes into account the results of the international consultation and the work of the Legal Commission of IBC.

## PART I

### SUMMARY OF REPLIES TO THE QUESTIONNAIRE

#### I. Aims of the Declaration on the Protection of the Human Genome

##### *I.1 What, in your view, should the basic aims of protection of the human genome be, as regards international law?*

*OBSERVATION 1: Protection of the Dignity and Rights of the Individual*

Reservations were expressed with regard to the stated purpose of the declaration - the protection of the human genome. It was observed that what should be protected is the dignity of the individual and his or her fundamental rights in relation to the development of human genetics and not the biological basis of human identity. A declaration whose purpose is the protection of the human genome may be interpreted as endorsing the tenets of genetic determinism. The wording is ambiguous and even unfortunate because it tends to sanctify the human genome as an entity in itself.

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25. See Annex IV.

26. The list of individuals and organizations who have submitted written comments on the revised outline is presented in Annex VII.

27. See Annex VIII.

## Response

The protection of the human genome is aimed above all at preserving human dignity and fundamental human rights and rejects any notion of genetic reductionism. The declaration goes on to emphasize that it is the duty of the international community to ensure the protection of the human genome against all forms of experimentation or use that are incompatible with respect for human dignity, a fundamental principle of bioethics. Nevertheless, it is true that the wording is ambiguous.

It was accordingly agreed to modify the title of the declaration, which now reads: 'Universal Declaration on the Human Genome and Human Rights'.

### *OBSERVATION 2: Genetic Diversity of the Human Species*

The protection of the human genome should encompass the safeguarding of the genetic diversity of the human species.

## Response

It does not seem appropriate to elevate the genetic diversity of the human species to the status of an intrinsic value, as has been done with regard to biological diversity in the United Nations Convention on Biological Diversity (cf. paragraph 1 of the Preamble which refers to the 'intrinsic value of biological diversity'). Doing so might sanctify the biological aspect of human beings, as a value in itself, to the detriment of their dignity as free and responsible individuals.

### *OBSERVATION 3: Principle of the Intangibility of the Human Genome*

The protection of the human genome must guarantee its intangibility.

## Response

According to the declaration, the purpose of protecting the human genome is to safeguard the 'integrity of the human species'. By virtue of that principle, any attempt to transform the identity of the human species would be unacceptable. Any experiments for the purpose of creating hybrids or chimeras must be prohibited.

The principle of the intangibility of the human genome would, furthermore, prohibit any intervention aimed at modifying the transmissible genetic heritage of a human being. In the present state of scientific knowledge, there can be no doubt that any experiment designed to transmit to future generations human genetic characteristics modified by human intervention is ethically unacceptable, even for therapeutic purposes. The principles set forth in the declaration rule out the possibility of such experimentation: the rigorous standards and special caution to which researchers must conform and the obligation to assess systematically the risks and benefits of any intervention involving the human genome. Nevertheless, the principles underlying this cautious stance might be reconsidered in the light of decisive scientific developments.

## ***1.2 What conclusions do you draw from consideration of the human genome as forming part of the common heritage of humanity, and do you feel that it is appropriate to consider it so?***

### *OBSERVATION 1: Human Rights and the Common Heritage of Humanity*

The fundamental rights of the individual, rather than the human genome, should be considered as forming a basic part of the common heritage of humanity.

## Response

In addition to its consequences for individual dignity and rights, the development of research on the human genome might affect the very integrity of the human species. By considering the human genome as part of the common heritage of humanity, the declaration underscores its universal value for humanity.

Moreover, the UNESCO General Conference, in 28 C/Resolution 0.12 of 13 November 1995 on the Medium-Term Strategy for 1996-2001, reaffirmed the 'urgent need to strengthen the moral solidarity of mankind in order to safeguard its common heritage - natural and cultural, tangible and intangible, intellectual and genetic' (par. 6).

**OBSERVATION 2: Rights of Individuals with Regard to Their Genetic Heritage**

The idea of the human genome as part of the common heritage of humanity might limit the right of individuals to dispose freely of their genetic heritage, in particular to transmit it to their descendants. It might be invoked by certain States in support of authoritarian measures, especially in the fields of public health and demographic policy.

**Response**

The declaration could not under any circumstances be used to justify authoritarian interventions affecting the human genome of an individual, even in the interests of public health.

The concept of the human genome as part of the common heritage of humanity is designed to establish a dynamic balance between the protection of the inalienable rights of the individual and the common interests of humanity. The indivisibility of those values must be underscored: the rights of the individual with regard to his or her genome are subject solely to constraints arising from the need to respect the rights of others.

The declaration affirms that every individual has freedom of choice with regard to any operations affecting his or her genome and the confidentiality of individual genetic data vis-à-vis a third party. The words 'operation affecting a person's genome' must be understood here *lato sensu*, that is, including the carrying out of genetic testing, which must be subject to the consent of the person concerned.

It was decided, nevertheless, to give greater emphasis in the declaration to the dual nature of the human genome as common heritage of humanity and a genetic heritage belonging to each individual.

**OBSERVATION 3: The Human Genome Can Never Be an Exploitable Resource**

Under international law, the expression 'common heritage of humanity' is applicable to resources the use of which it is deemed desirable to regulate in the interests of humanity as a whole. It would hardly seem appropriate, with regard to the fundamental objective of the protection of human dignity and rights, to consider the human genome as being equivalent to an economic resource the use of which must be controlled at the international level.

**Response**

The concept of common heritage was introduced into international law for the purpose of characterizing property considered to be of universal interest and which the international community is duty-bound to safeguard.

The concept of common heritage was, it is true, first used in international law in relation to outer space and its resources and was subsequently applied to certain environmental resources, such as the biosphere. However, the concept of a common heritage has also been enshrined by international law in the areas of culture (UNESCO Constitution of 16 November 1945, UNESCO Convention for the Protection of the World Cultural and Natural Heritage, of 16 November 1972, and the UNESCO Declaration of the Principles of International Cultural Co-operation of 4 November 1966, which states in Article 1, paragraph 3, that 'all cultures form part of the common heritage belonging to all mankind') and human rights (Resolution 3/03 of the twenty-first session of the UNESCO General Conference of 24 October 1980 and the Preamble of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950).

The concept of the common heritage of humanity is thus designed essentially to ensure the preservation of universal values. Thus, by characterizing the human genome as common heritage of humanity, the declaration is following the tradition of the legal texts already mentioned (cf. also Observation 1 above).

**OBSERVATION 4:**     *Patentability of the Human Genome*

The precise scope of the concept of the common heritage as applied to the human genome has not yet been defined clearly, in particular with regard to the patentability of the human genome. It would therefore be advisable to give express recognition to the principle of the non-patentability of the genome.

**Response**

Classifying the human genome as part of the common heritage of humanity serves as a reminder that knowledge about the human genome can never be the privilege of an élite but must benefit humanity as a whole. It helps to ensure free access to research data on the human genome.

The principle of free access does not, however, exclude the possibility of patenting the results of genome research. Free access to such results can be guaranteed while respecting intellectual property rights. Indeed, there are those who maintain that patenting is the best way to ensure free access because scientific data concerning patented inventions is automatically available for scrutiny.

In terms of the classic distinction in patent law between inventions, which may be patented, and discoveries, which cannot, the question remains as to whether the results of human genetic research can be patented. The implications are both legal and ethical.

From a legal standpoint, only inventions can be patented, as opposed to discoveries. Yet, in the field of genetics, it has become increasingly difficult to establish a clear dividing line between the two. Isolating and defining a protein-coding gene is not, in fact, a mere discovery.

With regard to ethics, the principle according to which the human body and its elements and products are not part of the heritage, as set forth in some domestic codes, would theoretically proscribe the patentability of human genes.

The current debate on the patentability of human genes is a complex one. The basic problem is to determine how, in that area, to best serve the interests of humanity as a whole. From a legal point of view, it would be difficult to assert that use of the term common heritage automatically excludes any possibility of patenting genome research. Nor should patenting be ruled out entirely because it may serve to stimulate genome research on which future therapeutic progress depends.

Finally, UNESCO is not mandated to resolve the issue, which primarily concerns the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

## **II. Human Rights and Human Genetics**

### ***II.1 According to the major international instruments, human rights are based on recognition of the dignity and freedom of human beings. How far should these principles be applied to the protection of the human genome?***

**OBSERVATION:**     *The Right of the Individual to Respect for his or her Genetic Heritage*

A consensus seems to be emerging to the effect that, in terms of the development of human genetics, protection of the individual should be based on the recognition of his or her dignity and freedom, which gives rise to the following principles: rejection of any discrimination based on genetic characteristics, free consent, and confidentiality of identifiable genetic data.

It was suggested, nevertheless, that such protection should be reinforced by incorporating in the declaration the right of each individual to respect for his or her genetic heritage and the freedom to transmit it to his or her descendants.

## Response

The point of including in the declaration the principle of the right of everyone to respect for his or her genetic heritage is to eliminate any risk of compelling individuals to undergo diagnostic, preventive or therapeutic operations in the interests of society.

This concern has already been taken into account in the declaration, which states that no operation affecting a person's genome may be undertaken 'without the prior, free and informed consent of the person concerned or, where appropriate, of his or her duly authorized representatives' and that 'no one may be subjected to discrimination on the basis of genetic characteristics'.

It does not, therefore, appear essential to affirm in the declaration the right of individuals to respect for their genetic heritage as that right might be confused with the right to the intangibility of the genetic heritage.

### **II.2 In your view, what 'eugenic practices contrary to the dignity or freedom of human beings' should be proscribed by the declaration?**

#### **OBSERVATION: Non-Therapeutic Reasons**

The suggestion was made to include in the declaration an express prohibition against any selection of genetic characteristics which cannot be justified on therapeutic grounds.

## Response

It is important in this regard to make a distinction between selection in the form of germ-line gene intervention, which will be dealt with later, and other types of selection, to be discussed below. The question is whether to leave open the possibility for individuals to affect the genetic heritage of their descendants for other than therapeutic reasons.

If the answer is no, there is a risk of leaving the door open to *de facto* eugenics which, while not necessarily taking the form of organized selection, might result from social conformity and the influence of prevailing social models.

If the answer is yes, can it be indisputably asserted in every case that the selection of genetic characteristics for non-therapeutic purposes is necessarily a violation of human dignity? In selecting the sex of a child, for example, the wish of parents who already have three boys to give birth to a girl does not appear to be a clear breach of respect for human dignity.

Under these circumstances, it would seem preferable to retain the possibility of non-therapeutic interventions as long as such operations respect human rights and dignity.

### **II.3 What principles should be reaffirmed with a view to guaranteeing human rights in cases where genetic research involves human beings or in the case of any other biomedical operation on the genome of a human being?**

#### **OBSERVATION: Protection of Individuals and Responsibility of Actors**

The majority of those who replied agreed that recognition of human dignity and fundamental human rights should form the basis for the protection of individuals in the context of operations involving their genome.

Some were of the opinion that, in view of the special risks involved, the conditions governing any intervention affecting the genome of an individual should be more precisely defined in the declaration. From an ethical standpoint, it would be unacceptable for such interventions to be undertaken lightly. Accordingly, they should be subject to specific precautions to ensure the protection of the individuals undergoing them. In particular, it would seem essential to require in every case a prior assessment in which the expected risks and benefits would be weighed.

In addition, some respondents maintained that the principle of compensation for any injuries sustained to the genome could, paradoxically, result in the banalization of this type of intervention and its potential risks, thereby minimizing the responsibility of those carrying out the operation.

### Response

The declaration should provide greater security for individuals undergoing operations affecting their genome.

It is therefore appropriate to support the proposal according to which any intervention affecting the genome of an individual would be subject to a prior assessment of its potential risks and benefits.

Moreover, it was decided to replace the right to compensation by the broader right to just reparation.

## **III. The Status of Researchers**

### **III.1 Do researchers have specific obligations with respect to human genetics? If so, which?**

#### *OBSERVATION: Monitoring High-Risk Research*

Many respondents stressed that in carrying out their research work, researchers must respect the legislative provisions in force and the ethical rules of their profession, which ensure the protection of the individual in the developed countries. Nevertheless, some respondents raised the question of the decentralization of high-risk research to countries with a weak democratic structure and of clandestine research. It was incumbent on researchers to combat drifts of that kind.

### Response

It is, of course, vital to combat such drifts. For that reason the declaration affirms the basic principle of the responsibility of researchers, which must necessarily arise in the event of injuries to the genome, and the duty of States to regulate research activities whenever it is necessary to do so in order to safeguard human dignity and protect health and the environment. In addition to these provisions, Article 10 sets forth the principle of the right to reparation. Scientific and cultural co-operation between States should also give rise to appropriate measures.

### **III.2 Should the principle of freedom of research be limited as regards genetics?**

#### *OBSERVATION: Regulation of Genetic Research*

In addition to its role in safeguarding human dignity and freedom and protecting health and the environment, the declaration should, it was proposed, prohibit genetic research for military purposes and research involving intervention on the cells of the human germ-line.

### Response

It was decided to expressly condemn research for military purposes in the preamble of the declaration.

The question of research involving interventions on the human germline should be examined, first of all, in the context of the debate on the intangibility of the human genome. Moreover, research on the cells of the human germline does not necessarily imply modification of them; nor does it mean, even in such a case, that those modifications would actually be transmitted. A general prohibition on research on germline cells would therefore seem inappropriate. Lastly, the intent of the declaration is to set forth guidelines and not to regulate practices in the biomedical field. The declaration is therefore not the best framework in which to deal with this question.

## IV. Solidarity and International Co-operation

### IV.1 *What practical form should the duty of solidarity affirmed by the declaration take with regard to the aims of the protection of the human genome?*

**OBSERVATION:**            *Duty of Solidarity*

At the national level, the majority of respondents were in agreement as to the importance of the duty of solidarity with respect to persons at risk, in particular in the areas of access to employment, social benefits and education. Many emphasized the importance of respecting the freedom of choice of such individuals with regard to the use of genetic testing and any interventions that might result from it.

It was proposed that, in order to give material expression to the principle of solidarity in a world facing the risks arising from advances in genetics, the declaration should endorse the creation of independent ethics committees, with pluralistic and multidisciplinary membership, mandated to identify the ethical, social and human issues raised by research and interventions affecting the human genome.

Response

This proposal, which will unquestionably contribute to respect for the principles set forth in the declaration, was incorporated into a new article 15.

### IV.2 *What, in your view, are the most appropriate forms of international co-operation for protection of the human genome? In particular, what role should be played by co-operation in information and education?*

**OBSERVATION:**            *International Co-operation*

Frequent emphasis was laid on the importance of disseminating scientific knowledge about the human genome. It was suggested that some form of control of genetic research should be established at the international level.

Response

A declaration cannot lay down binding conditions for the control of genetic research. States can only be asked to undertake to provide a framework within which genetic research is carried out safely and respects human rights. The International Bioethics Committee will monitor the implementation by States of these commitments.

## V. Other Remarks

### V.1 *Absence of a definition of the human genome*

*Observation*

The declaration does not contain a definition of the human genome. It would be appropriate to specify in each article what is meant by the human genome in order to clarify the precise scope of the term.

Response

As understood in the declaration, the human genome includes both the genetic make-up of humanity as a whole and of the individual, genes in their tangible form (genetic material) and genes in their intangible form (genetic information).

In Article 1, the concept of 'the human genome, common heritage of humanity' encompasses all of these meanings. The point is to present the human genome as a universal value which it is the duty of the international community to safeguard, taking account of this expression in its diversity - individual and collective, tangible and intangible.

## PART II OBSERVATIONS AND COMMENTS

### Title of the Declaration

The title of the declaration should be changed so that it emphasizes the protection of human rights rather than protection of the human genome.

#### Analysis

The basic purpose of the declaration is to ensure that the development of genetics takes due account of the need to protect human rights. It is therefore appropriate to emphasize in the title the protection of human rights rather than the protection of the human genome.

### Preamble

1. The single reference to 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, is clearly insufficient to prohibit the use of genetics for military or bellicose purposes. Express mention must be made of this in the text of the declaration.

#### Analysis

It would be advisable to emphasize in the preamble that genetics must not be used for military or bellicose purposes.

2. References to international instruments on the protection of intellectual property rights should be eliminated since they weaken the concept of the human genome as the common heritage of humanity.

#### Analysis

It would not be advisable to eliminate those references: under certain circumstances, which remain to be defined, in particular by the competent international organizations such as WIPO and WTO, research on the human genome might, as appropriate, fall within the scope of intellectual property law.

3. Mention should be made in the declaration of the need to protect human genetic diversity.

#### Analysis

Human genetic diversity is a fact rather than a value which needs to be protected as such, along the same lines as human dignity and human rights. It is, nevertheless, important to emphasize in the declaration that the existence of genetic diversity may not give rise to any interpretation of a social or political nature that runs counter to the recognition of the equal dignity of all members of the human family.

4. The reference to the prospects opened up by genetics for 'reducing inequalities throughout the world' is highly ambiguous and should be amended.



Analysis

In order to prevent this formulation from being misused for eugenic purposes, it was decided to refer to the prospects offered by genetics for 'improving the health and well-being of individuals and of humankind as a whole'.

**Operative Part****Article 2**

Greater emphasis should be given to the fact that the human genome, which is the common heritage of humanity, is also a heritage constituting the specific genetic identity of each individual (which prohibits it from being considered as property subject to collective appropriation).

Analysis

The principle underlying this proposal, which is fully relevant, was endorsed by inserting after Article 1 the following: 'The genome of each individual represents his or her specific genetic identity'.

**Article 3**

Certain respondents noted that, having no normative consequences, Article 3 belonged in the preamble.

Analysis

Article 3 confirms the rejection of genetic determinism enunciated in Article 2. By emphasizing the influence of living conditions on the development of the genetic potentialities of individuals, it underlines the importance for individuals of an environment conducive to the development of their genetic potentialities.

**Article 4**

The purpose of Article 4 should be not only to protect the dignity of individuals but also to protect their rights.

Analysis

The fundamental texts of international human rights law are in fact based on reference to both the dignity and the rights of the individual (cf. the Preamble of the United Nations Charter, the Universal Declaration of Human Rights, etc.). The proposed modification would in addition eliminate any possibility of deviating from the principle of dignity by limiting individual rights with respect to the implications of genetics.

Consideration must be given to the possibility that certain States might make use of the concept of the dignity of the individual for eugenic purposes, for example by asserting that certain types of genetic disabilities are incompatible with human dignity. More generally, it is not possible to eliminate entirely the risk that the concept of the dignity of the individual - which is not defined under positive law - might be used, where appropriate, as grounds for unwarranted restrictions on the principle of freedom of choice. It therefore seems advisable to affirm that individual dignity and rights, including individual freedom, are indissociable values.

**Article 5**

It should be made clear that genetic research also has the function of advancing knowledge.

Analysis

It would indeed be logical to attribute the same functions to genetic research in Article 5 and Article 11.

## **Article 7**

1. Article 7 should state that only those interventions affecting the human genome which are undertaken for therapeutic purposes may be authorized.

### Analysis

While interventions affecting the human genome undertaken for 'scientific purposes' may be called into question, it is essential to maintain the possibility of carrying out research on the human genome. In any event, such research cannot run counter to respect for human dignity and freedom, in accordance with Article 6. That is, moreover, the position taken by various ethics committees throughout the world. The French National Consultative Committee on Ethics in the Life and Health Sciences (CCNE) has, for example, recently acknowledged the validity of scientific purposes with regard to the use of genetic testing.

2. Any intervention affecting the human genome must be preceded by a risk and benefit analysis.

### Analysis

This proposal is entirely relevant. It has even been reinforced by the requirement of a 'rigorous and prior assessment of the risks and benefits pertaining thereto' rather than a mere analysis.

3. Article 7 should be supplemented by the following words: '... and without prior, free and informed consent of the person concerned or his or her duly authorized representatives or, where appropriate, his relatives or family members'.

### Analysis

These additional details are intended to adapt the requirement of individual consent to the social system in many countries where the nuclear or extended family and the community or group play a fundamental role. Nevertheless, it appeared preferable in a situation involving the physical integrity of the individual and of his or her descendants to stick to the idea of 'duly authorized representatives', who may of course be members of the family.

4. The declaration should specify that the consent of the duly authorized representatives may not be granted unless it is guided by the interests of the person concerned.

### Analysis

It would not be appropriate in the framework of the future declaration to go into the details of medical practice, in particular the issue of interventions to which incompetent persons might be subjected. However, it would be useful to stress that the consent of the duly authorized representatives must be guided by the 'best interests' of the person concerned (the expression used in the United Nations Convention on the Rights of the Child, of 20 November 1989, referred to in the preamble).

## **Article 8**

Article 8 should specify that discrimination based on the best interests of the individual may be acceptable. The example cited is that of a person who is refused employment because the job might expose him or her to material which is known to contribute to the development of an illness to which the person concerned is predisposed by virtue of genetic characteristics. It should therefore be specified that only unjustifiable discriminatory action is prohibited. It is a fact that aptitude for a particular job may very well depend on specific physical characteristics which are genetically based, such as good eyesight.

### Analysis

The purpose of the ban on discrimination is not, in principle, to prevent derogations arising from legitimate causes or in the interests of the individuals concerned. None the less, in an effort to clarify that issue, it was decided to specify that the only cases of discrimination which are prohibited are those which aim at or have the effect of 'injuring the recognition of human dignity or the enjoyment of his or her rights on the grounds of equality'.

## **Article 10**

The right to compensation should be replaced by the right to just reparation.

### Analysis

Since the term 'reparation' is broader in scope than 'compensation', this proposal would strengthen the protection of individuals in the case of injuries sustained as a result of an operation affecting their genome. In addition, the term 'just' takes into account the particular circumstances under which the injury occurred, as opposed to an inclusive evaluation. Lastly, in order to prevent the descendants of an individual from making claims against him or her, it should be specified that the injuries for which reparation may be requested must be the 'direct result' of an intervention affecting the genome of the person concerned.

## **Article 11**

1. Because of its ambiguity, as explained in relation to Article 5, the reference in Article 11 to 'prevention of disability and disease' should be deleted.

### Analysis

The revised version of Article 11 takes into account the objections raised and includes the same functions as those mentioned in Article 5.

2. It is not appropriate to impose on States a positive obligation to encourage genetic research.

### Analysis

The revised version of Article 11 reflects the desire to provide researchers with the intellectual and material conditions they need to carry out research on the human genome.

## **Article 14 bis**

There should be an additional article designed to promote the establishment of ethics committees to identify the various issues raised by research and interventions affecting the human genome.

### Analysis

This proposal is clearly valuable since many countries do not yet have ethics committees. In the current version, the proposal has been incorporated into the new Article 15.

## **Article 15**

It might be appropriate to replace the rather vague expression 'scientific culture' by 'scientific knowledge', which would encompass the results of genetic research, as defined in the new Article 16.

### Analysis

By ensuring access to scientific knowledge concerning the human genome, the proposed wording would have the advantage of giving greater substance to the notion of the common heritage of humanity.

## **Article 16**

The previous version of Article 16 should be amended to refer not only to promoting specific teaching but also specific research in order to encompass more fully the various implications, and foundations, of human biology and genetics.

### Analysis

The new Article 17 incorporates this proposal.

**Article 18**

States should not be required to adopt normative measures to meet the purposes of the declaration.

**Analysis**

It is, indeed, for States to decide on the most appropriate means of ensuring respect for the principles set forth in the declaration. The new Article 19 incorporates this principle.

**Article 21 bis**

The declaration should include an article prohibiting the use of the provisions of the declaration for ends contrary to the principles set forth in it.

**Analysis**

This proposal is reflected in the new Article 23.

# MECHANISM FOR MONITORING THE FUTURE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

(1st July 1996)

*by Héctor Gros Espiell*

## I. Introduction

1. The framework for drawing up an international instrument on the human genome is very broad. It is in the nature of a number of principles - those principles that form the basis of the common rights on which the international community is founded: human dignity, freedom, equality of rights and fellowship among individuals and peoples.

2. Few countries have so far adopted legislation in the field of bioethics. It was felt better from every standpoint to promote a framework of principles that would ensure internationally harmonized legal provisions in this area rather than allow differing practices - whether *de jure* or *de facto* - to develop. The International Bioethics Committee of UNESCO (IBC) believed it preferable to begin by drawing up an instrument in the form of a declaration which seemed most appropriate to the aim in view - that of winning the support of the international community on a number of main principles. What is more, an instrument not requiring ratification, accession or acceptance, is likely to be adopted more quickly than a formal agreement, whereas the binding nature of a convention could well discourage certain States from committing themselves in so complex and changeable an area. Lastly, as far as the issues at stake in the protection of the human genome are concerned, there is every justification for the adoption of a declaration: United Nations doctrine considers that 'a declaration is a formal and solemn instrument that is justified on infrequent occasions when principles of major importance and lasting validity are being stated ... with stress laid on moral authority'. The instrument thus drawn up will therefore be pragmatic and open to the changes made necessary by scientific progress whilst allowing for cultural and religious differences and founding itself on the great universal principles.

3. The declaration formula was also chosen because of the flexibility it affords without ruling out the possibility of giving legal power to its provisions. Section G of the future declaration, for example, entitled 'Implementation of the Declaration', sets out the undertakings that States could enter into on adopting the declaration. In that context, the monitoring system that is decided upon, in addition to providing a framework for the application of the future declaration by Member States, will be a vital factor for the adoption of its principles in national legislation. Again, the rapid pace of progress in genetics is another valid reason for having a suitable mechanism. The IBC therefore decided to consider possible ways of monitoring the future declaration, a responsibility with which it would be charged by the declaration.

4. This paper describes a number of systems established under the terms of the main international instruments for the protection of human rights and the procedures for considering communications regarding violations of human rights in UNESCO's fields of competence, together with examples of certain procedures in force for monitoring the application of standard-setting instruments adopted within the framework or under the aegis of the Organization. Lastly, some suggestions are made as to ways in which the application of the future declaration might be monitored.

## II. Precedents

### II.1 *At the Universal Level*

5. In some cases, within the framework of the United Nations and where brought by Member States, the International Court of Justice may refer in its judgements, which are binding on Member States, to questions concerning human rights. The procedures for the protection of the latter set up by the United Nations may be defined as mechanisms for conciliation, mediation and good offices. In general, the sanctions applied by the United Nations are often of a moral nature, although there have been times when international bodies have, as needed, applied pressure of various kinds on their Member States. What is more, in the event of a State's flagrant and systematic violation of human rights, the publication of information about such situations itself contributes towards the protection of human rights. Complaints brought before the United Nations by individuals or groups of individuals go to the United Nations Centre for Human Rights which considers them and refers them to the responsible body. This comes before the application of the extra-conventional procedures that have been developed within the United Nations (cf. Section D below for conventional procedures).

6. Generally speaking, the individual communications regarding human rights constitute either a source of information enabling the body receiving them to draw up a report on the general human rights situation in a given country, or else petitions to an international non-jurisdictional body.

#### A. United Nations Commission on Human Rights

7. The setting up of suitable procedures for considering individual communications regarding alleged violations of human rights was envisaged right from the very first meeting of the Commission on Human Rights (January-February 1947). A subsidiary body of the United Nations Economic and Social Council (ECOSOC) established by a resolution dated 16 February 1946, the United Nations Commission on Human Rights consists of representatives of States elected by ECOSOC for a period of three years. The States submit reports on a triennial basis: the first year on civil and political rights, the second on economic, social and cultural rights and the third on freedom of information. The Commission meets annually. As part of the general United Nations machinery, it is the principal body for monitoring the observance of human rights. It consists of government representatives from fifty-three Member States, so it is thus a political body. Its meetings are attended by representatives of the Specialized Agencies and observers from international non-governmental organizations with advisory status in the United Nations.

8. The communications received by the United Nations are, in principle, divided into two categories:

- a) those dealing with the principles on which universal and effective respect for human rights is based, and
- b) those whose common feature is their denunciation of violations of human rights.

9. The procedure known as 'Procedure 1503' established by the Economic and Social Council applies to the second of these two categories. UN procedures applying to the consideration of individual communications are defined in a set of provisions contained in ECOSOC Resolution No. 1503 (XLVIII) of 27 May 1970, based on a draft produced by the Sub-Commission on Prevention of Discrimination and Protection of Minorities and combined with Resolutions 728F (XXVIII) and 1235 (XLII), dated 30 July 1959 and 6 June 1967 respectively. The procedure is in three stages.

#### I) EXAMINATION OF COMMUNICATIONS BY A SPECIAL WORKING GROUP OF THE SUB-COMMISSION ON PREVENTION OF DISCRIMINATION AND PROTECTION OF MINORITIES

10. This working group, with a maximum of five members, meets once a year in private meeting to consider all communications (satisfying the conditions of admissibility laid down by the Sub-Commission) and the replies from the governments of the States concerned. By simple majority vote, it then retains for further attention those communications which appear to reveal a consistent pattern of gross and reliably attested violations of human rights and fundamental freedoms meriting being brought to the attention of the Sub-Commission together, as necessary, with the replies of the governments of the States concerned.

II) EXAMINATION OF COMMUNICATIONS BY THE SUB-COMMISSION ON PREVENTION OF DISCRIMINATION AND PROTECTION OF MINORITIES

11. The Sub-Commission, in plenary meeting, then has to decide whether any particular situation exists which appears to reveal a consistent pattern of gross and reliably attested violations of human rights.

III) EXAMINATION OF COMMUNICATIONS BY THE COMMISSION ON HUMAN RIGHTS

12. The Commission is then required to determine whether any situation referred to it by the Sub-Commission requires a thorough study followed by a report and recommendations to ECOSOC. The Commission may decide that the situation requires investigation by an ad hoc committee which shall be undertaken only with the express consent and co-operation of the State concerned under conditions determined by agreement with it. The committee may strive for friendly solutions before, during and even after the investigation and may include in its report to the Commission such observations and suggestions as it may deem appropriate.

13. It should be noted that the procedure remains confidential up to the moment when the Commission on Human Rights makes its recommendations to ECOSOC.

**B. United Nations Human Rights Committee**

14. Set up in accordance with Article 28 of the International Covenant on Civil and Political Rights adopted by the General Assembly of the United Nations on 16 December 1966, the United Nations Human Rights Committee is responsible for the implementation of this covenant. It is composed of eighteen members from the States Parties to the Covenant elected in their personal capacity to serve four years. They are eligible for re-election. The members of the Committee have to be persons of high moral character with recognized competence in the field of human rights. Under Article 40 of the Covenant, the Committee is required to study the reports submitted by States Parties to the Covenant on the measures they have adopted to give effect to the rights recognized therein and on progress made in the enjoyment of those rights. The Committee may also request such reports as it considers necessary and useful and make any necessary comments thereon. It may transmit to the Economic and Social Council its general observations on the reports received from States Parties to the Covenant. It is also required to submit a general report on its work each year to the United Nations General Assembly, via ECOSOC. The Committee also has the right to examine communications in which a State Party claims that another is not fulfilling its obligations under the Covenant.

15. The Optional Protocol to the Covenant enlarges the powers of the Committee by enabling it also to examine communications from individuals. The Human Rights Committee carries out such examinations in private meetings.

A) CONDITIONS FOR THE ADMISSIBILITY OF COMMUNICATIONS FROM INDIVIDUALS

16. Under the terms of the protocol and the Committee's internal rules, to be admissible communications have to satisfy several conditions:

- they may not be anonymous;
- they have to come from one individual or from groups of individuals under the jurisdiction of a State Party to the Covenant;
- individuals have to prove that they are victims of a violation of one of the rights listed in the Covenant by the State Party to the Covenant; they are required to present their communication personally (but they may be represented by another person);
- communications must not constitute an abuse of the rights of submission of such communications;
- communications must not be incompatible with the provisions of the Covenant;
- they must not be under examination under another procedure of international investigation or settlement;
- they have to show that all available domestic remedies have been exhausted.

## B) TREATMENT OF COMMUNICATIONS FROM INDIVIDUALS

17. The Secretary General of the United Nations (represented by the Assistant Secretary General, Centre for Human Rights in Geneva) is authorized to request further information from the writers of communications.

18. Examination of communications is in four stages.

### i) *Examination by a working group*

19. This working group, consisting of a maximum of five members of the Committee, considers the cases submitted by the Secretariat and decides:

- whether additional information needs to be elicited from the writers on certain aspects regarding admissibility;
- whether the communications need to be transmitted to the governments of the States concerned;
- whether the governments need to be asked to make their comments or to provide information on the admissibility of the communications;
- whether to recommend the Committee to state its views on any of the possibilities listed above, to declare any particular communication inadmissible or to break off the consideration of some other communication on the grounds of insufficient information.

### ii) *First examination by the Committee*

20. The Committee makes its decision on the recommendations put forward by its working group. It may take a different decision from that proposed. It may also appoint a special rapporteur for a particular communication.

### iii) *Examination prior to decision on admissibility*

21. Once the information requested has been gathered, subsequent to the first examination, the Committee looks at the communications again in the light of the recommendations made by the working group or the special rapporteur. It may then decide whether the communications are admissible, whether their examination should be interrupted or suspended and whether other information should be requested either from their writers or from the governments of the States concerned. A communication may be declared admissible only when the government of the country concerned has had an opportunity to make its comments known and to put forward any information it considers relevant.

### iv) *Substantive examination*

22. Should the Committee declare a communication to be admissible, its writers and the governments of the States concerned are notified and they may then provide explanations or take the steps necessary to restore the rights alleged to have been violated. In all cases the Committee is always required to adopt the principle of equality of means by giving the governments of the States concerned and the writers of communications the opportunity to put forward their respective observations. Following the substantive examination, the Committee sets out its findings and forwards its views to both parties.

## C. United Nations Committee on Economic, Social and Cultural Rights

23. Under Resolution 1985/17, the Economic and Social Council established the Committee on Economic, Social and Cultural Rights consisting of eighteen members elected in their personal capacity for four years by the Council from a list of persons nominated by States Parties to the International Covenant on Economic, Social and Cultural Rights adopted by the United Nations General Assembly on 16 December 1966. The members of the Committee have to be experts with recognized competence in the field of human rights.



24. The Committee's primary function is to consider the reports submitted by States Parties to the Covenant on the measures they have taken and the progress achieved with regard to the rights set out under Articles 16 and 17 of the Covenant and in accordance with the decisions and resolutions of ECOSOC. The reports are addressed to the Secretary-General of the United Nations, who forwards a copy, together with a summary of its examination, to the Economic and Social Council for consideration in accordance with the provisions of the Covenant.

25. The Secretary-General also sends the Specialized Agencies a copy of reports from States Parties to the Covenant who are also members of those agencies insofar as such reports relate wholly or in part to questions falling within their competence under the terms of their respective constitutions. It is then the responsibility of the Specialized Agencies to submit their report on the questions raised in order to assist ECOSOC in fulfilling its obligations under Articles 21 and 22 of the Covenant. In their reports, States Parties are entitled to draw attention to the factors and difficulties preventing them from complying fully with the obligations laid down in the Covenant. They also have the right, when their reports are being considered by the Economic and Social Council, to attend the Committee's meetings, make statements on the reports they submit and reply to questions put to them by the members of the Committee.

#### D. Procedures Laid down in United Nations Conventions

26. As already pointed out, monitoring mechanisms and procedures for considering individual communications regarding human rights already exist by virtue of certain United Nations agreements. They operate within specific treaties requiring, each within its own structure, the setting up of a specific committee. The members of these committees are experts elected by the States Parties to the different instruments from among persons well known for their high moral character and impartiality or with recognized competence in the field covered by the convention concerned. These monitoring bodies consider reports submitted by States Parties to the following conventions:

- i) the International Convention on the Elimination of all Forms of Racial Discrimination (21 December 1965), in which Articles 8-15 provide for the establishment of a Committee on the Elimination of Racial Discrimination and set out how it should operate;
- ii) the Convention on the Elimination of all Forms of Discrimination against Women (18 December 1979), which has similar provisions in Articles 17-22 regarding the establishment and functioning of the Committee on the Elimination of Discrimination against Women;
- iii) the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (10 December 1984), in which Articles 17-24 indicate how the Committee against Torture should operate;
- iv) lastly, the Convention on the Rights of the Child (20 November 1989), in which Articles 43-45 describe the way in which it should be implemented by the Committee on the Rights of the Child.

#### E. UNESCO Committee on Conventions and Recommendations

27. At its seventy-first session, in 1965, the Executive Board decided to set up a 'special committee on discrimination in the field of education'. With the passage of time the rules and terms of reference of this committee changed and it has now become a standing committee of the Executive Board known as the Committee on Conventions and Recommendations (the CR Committee). The Committee on Conventions and Recommendations, a subsidiary body of the Executive Board, consists of thirty representatives of Member States of the Organization with seats on the Executive Board, drawn from all the electoral colleges of the Board. The CR Committee holds two regular meetings a year, any extraordinary meetings being decided upon by the Executive Board.

28. By its Decision 104 EX/3.3, the Executive Board mandated this committee, among other things, to consider communications received by the Organization concerning questions of violations of human rights as set out in Articles 19, 26 and 27 of the Universal Declaration that fall within UNESCO's fields of competence. Paragraph 7 of this decision says that UNESCO should act in a spirit of international co-operation but not play the role of an international judicial body.

29. Thus, in addition to all matters relating to the application of UNESCO's standard-setting instruments referred to it by the Executive Board, including the periodical reports submitted by Member States on the implementation of conventions and recommendations, the CR Committee considers communications concerning cases and questions of violations of human rights within UNESCO's fields of competence.

30. The consideration of these communications is a six-stage procedure. In accordance with established practice, to be judged admissible a communication has first to meet four conditions:

- *ratione personae*: the writer (victim or other person) of the communication, presented in its original form, must be perfectly identifiable and carry on an activity within UNESCO's fields of competence. The communication must refer to a specific case, not a general situation, and must not have been the subject of earlier representations to another body. In addition, the victim has to have been carrying on an activity within one of UNESCO's fields of competence at the time of the events complained of;
- *ratione materiae*: the writer must refer to one of the human rights mentioned in the Universal Declaration of Human Rights or one of the international covenants on human rights. Such right must be one that may be deemed to be of direct concern to UNESCO;
- *ratione temporis*: a certain time is allowed to permit the government concerned to prepare any observations it may wish to make prior to the meeting of the CR Committee;
- *ratione loci*: the communications must not only reach but must also be addressed to UNESCO. The alleged events must also have occurred on the territory of a Member State of the Organization.

The writer is asked whether he or she agrees that the procedure should go ahead and whether he has any objections to his or her name being divulged. The admissible communication is then forwarded to the government concerned and the dossier is sent to the CR Committee, which considers it in private meeting. The Committee's reports, together with its recommendations, are submitted to the Executive Board, also meeting in private meeting in order to maintain the confidential nature of the procedure. It should be noted that, in principle, 'cases' are considered by the Executive Board in private meeting, whereas 'questions' are considered by the Executive Board and the General Conference in meetings open to the public.

#### F. Monitoring of Action taken on Recommendations and Conventions of the International Labour Organization (ILO)

31. Every convention of the International Labour Organization constitutes the minimum basis of a recognized right of the workers of a State that is a party to it, since these rights, recognized at the international level, are guaranteed by each State's own laws and regulations. Mechanisms have been set up to ensure that States comply with their obligations.

32. At each of its meetings, the Committee on the Application of Conventions and Recommendations, consisting of independent persons, considers the reports submitted by Member States on the measures they have taken in respect of the obligations they have entered into. The Committee has a judicial role: it submits reports to the ILO Conference Committee on the Application of Standards. The most serious cases of non-compliance are referred by the Committee to the International Labour Conference.

33. Two possible adversarial procedures, depending on the nature of the complainant, apply to complaints of violations of conventions notified to the ILO.

a) The first enables employers' organizations and trade unions to file complaints against a State for unsatisfactory compliance with obligations undertaken in a convention. If the Governing Body judges the complaint admissible, it appoints an ad hoc committee to consider the complaint. The ad hoc committee is made up of members of the governing body in equal numbers from the three groups - governments, employers and workers. The three members of the ad hoc committee draw up a report and make recommendations to the Governing Body. After adversarial discussion, the latter may, with the participation of the accused government, make public the complaint and the reply, which brings the procedure to a close, or initiate the complaint procedure against the State concerned.

b) The second adversarial procedure applies to complaints that one ILO Member State may file against another 'if it is not satisfied that any other Member is securing the effective observance of any Convention which both have ratified'. Note that the Governing Body may also file a complaint, spontaneously or at the request of a delegate to the International Labour Conference, against a Member of the ILO. In-depth examination of complaints may be carried out by a Commission of Inquiry, which makes its recommendations. The governments concerned then have to say whether they accept them or not and, if not, whether they wish to put their dispute before the International Court of Justice.

34. In 1950, because of the importance of freedom of association to workers in the defence of their rights, the ILO, in agreement with ECOSOC and UNESCO, introduced a special procedure applicable even to States that have not ratified the conventions ensuring the freedom of trade unions. This special procedure is put into effect by the Committee on Freedom of Association, whose members represent governments, employers and workers in equal thirds. The Committee is appointed by the governing body and has a total of nine members reflecting the tripartite nature of the Organization. It generally operates from its headquarters but it may, using the direct contact procedure and at the request or with the agreement of the governments concerned, do its work at other locations. Its role is to consider the facts complained of in the light of States' international obligations. It conducts inquiries and visits the accused State, provided the latter agrees (since some States have not signed the conventions).

35. In some cases, with the consent of the government concerned, the Committee on Freedom of Association may refer a complaint to the Fact-finding and Conciliation Commission for more thorough study. Complaints referred to this Commission may come from complainants who are not nationals of States which have ratified the relevant conventions. The Fact-finding and Conciliation Commission is the formal body that was set up when the mechanism for the protection of trade union rights was created in 1950. While its role is to consider complaints of violations of trade union freedom and is therefore investigative in nature, it may also, jointly with the government concerned, consider questions submitted to it for the purpose of solving difficulties by mutual agreement. In principle, no case may be put before the Commission without the consent of the government concerned.

## ***II.2 At the Regional Level***

### **A. The European Court and Commission of Human Rights**

36. The European Convention for the Protection of Human Rights and Fundamental Freedoms (4 November 1950), complete with its ten additional protocols, defines the procedures and bodies that protect it: the European Commission of Human Rights and the European Court of Human Rights. The Convention also confers decision-making powers and responsibility for monitoring the execution of the Court's judgements on the Committee of Ministers of the Council of Europe. The Convention contains two conditional clauses:

- i) a State has to give its explicit consent before it can be proceeded against for non-compliance by an individual or brought before the Court (Article 46);
- ii) petitions may be filed either by States or by individuals.

Procedures are identical in both cases.

37. The Commission consists of as many members as there are High Contracting Parties to the Convention (only one representative per State). The members are elected for a term of six years by the Committee of Ministers from a list of names drawn up by the Bureau of the Consultative Assembly of the Council of Europe on the proposal of the political groups in the Assembly.

38. Any State may inform the Commission of what it considers to be violations of the Convention by another High Contracting Party. Petitions may be filed with the Commission by any individual, group of individuals or international non-governmental organization that deems itself to be the victim of a violation of the Convention by a High Contracting Party, provided such State, under Article 25 of the Convention, has declared that it recognizes the authority of the Commission with regard to that procedure.

39. Petitions are examined for admissibility, which may raise some awkward legal problems, and to check their conformity with the provisions of the European Convention for the Protection of Human Rights and Fundamental Freedoms:

- i) the Commission may only deal with a petition after all domestic remedies have been exhausted;
- ii) no anonymous petitions may be dealt with;
- iii) the petition may not be the same as one submitted previously or one that is currently under examination by another international body;
- iv) the petition must not be incompatible with the provisions of the Convention or 'manifestly ill-founded or an abuse of the right of petition'.

40. The Commission plays a judicial role when deciding whether a petition is to be accepted or rejected, there being no appeal. In addition to its judicial powers the Commission also has a conciliatory function. When a petition is admissible, the Commission begins its thorough examination with all parties taking part. It may carry out an inquiry whose conduct the defendant government is required to facilitate. In this way the facts are established. At this stage the Commission does bring about amicable settlements and many petitions are withdrawn after the two parties have come to an agreement. Satisfaction can then be given to the petitioner, often through the payment of compensation and, in fact, the government frequently takes steps to change the legislation or practice complained of. The reason for these amicable settlements is that often the petitioning States have no wish to go on with the procedure while the Commission sees no way it can strike it off the rolls.

41. If the attempts at conciliation fail, the Commission makes out a report which sets down the facts and gives its view on whether the facts reveal a violation, on the part of the defendant State, of the obligations it is under. This report, which remains confidential, is forwarded to the Committee of Ministers of the Council of Europe and to the States concerned. The Commission's proposals accompany the report. Three months are then allowed for the Commission or one of the States concerned to refer the matter to the Court, provided the parties have agreed to be subject to the jurisdiction of the Court (Article 48), a possibility that Protocol 9 extends to individuals.

42. The second body that a case can be taken to is the European Court of Human Rights, which is strictly judicial in its activities. It was set up by the Convention in order to ensure compliance with the undertakings it imposes on its High Contracting Parties. It shares the responsibility for implementing the general guarantee with the Commission, but it alone is invested with legal powers. It consists of a number of judges equal to that of the members of the Council of Europe and elected by the Assembly for a term of nine years. They are eligible for re-election. The Court elects its President, draws up its internal rules, decides on its procedure and meets once yearly. It delivers judgements by majority against which there is no appeal. Hearings are held in public, the Court having adopted the principle of proceedings open to the public.

43. No direct approach may be made to the Court:

- i) the matter must first have been put to the Commission in the form of a petition;
- ii) it must have been declared admissible;
- iii) it must have been considered by the Commission; and,
- iv) the attempt at conciliation must have failed and the Commission must have drawn up its report recording the failure of the attempt at an amicable settlement.

44. The Court has general responsibility for matters concerning the interpretation and implementation of the Convention, bearing in mind the conditions determining the admissibility of petitions from States or individuals. Its authority extends over all High Contracting Parties that have signed the Convention stating its jurisdiction to be binding or which have given their consent or agreement for the Court to be involved in a specific case.

45. Under Article 48 of the Convention, cases may be taken to the Court by the Commission or by the High Contracting Party concerned, i.e. that of which the victim is a national, that which has appealed to the Commission or that which has been accused. No individual, even after the failure of the attempt at an amicable settlement, may file with the Court a matter which he or she has submitted to the Commission in the form of a petition, a restriction which is counterbalanced by the Commission's right to go to Court with a case.

46. Since the Court, therefore, can only be applied to by a State or the Commission, the sovereignty of a State cannot really be attacked. The European Court has tried to mitigate the drawbacks of this rule for the individual who, although never able to be a party in a case, is not wholly excluded from the procedure. The Commission's report, for example, is communicated to that person, who has access to the Court as witness and can be represented by defence council.

#### B. Inter-American Court of Human Rights and Commission on Human Rights

47. Set up in 1960 by the Council of the Organization of American States (OAS), the Inter-American Commission on Human Rights is an autonomous entity in the framework of the OAS. Under its Charter, its function is to promote respect for human rights as defined in the American Declaration of the Rights and Duties of Man (Articles 1 and 2 of the Charter of the Commission), in particular by making recommendations to the Member Governments of the OAS. The Commission, composed of seven members elected for a term of four years by the Council of the OAS and eligible for re-election (the members must be nationals of the Member States of the Organization of American States), has developed its function by dealing with individual complaints, carrying out inquiries on the situation of human rights in certain countries and adopting recommendations urging governments to put an end to violations of human rights.

48. The powers of the Commission were officialized in its 1966 Charter at a time when its priority was the protection of civil rights. The Protocol of Buenos Aires made the Commission an OAS body in the field of the protection of human rights. It holds an ordinary meeting once or twice a year. It exerts moral pressure by examining the human rights situation and making reports after investigations carried out on the spot by a 'Special Committee'. The reports are communicated to governments and, depending on the response, may be made public. This happens when a government fails to reply or if the reply is unsatisfactory. The Commission may forward a report to the Assembly of the OAS, which endeavours to augment its impact by adopting a resolution.

49. The Commission receives and considers individual petitions both from victims and from bodies defending the general interest. Its object is to achieve an amicable settlement based on respect for the rights enshrined in the American Convention on Human Rights. If no agreement is reached, it draws up a report containing recommendations which is forwarded to the States concerned. The latter have the right of reply. If there is no reply or the reply is unsatisfactory, the Commission may make its report public and transmit a copy to the Council of the OAS. The Commission can examine complaints from one government about another, provided that the two States concerned have explicitly accepted its power to do so as set out in the American Convention on Human Rights.

50. It should be noted that, while individual communications are examined as such, they are also material for assessing the general human rights situation in a particular country. On certain conditions, therefore, the Commission may instruct its Secretariat to carry out a comprehensive study of a given country.

51. The Inter-American Court of Human Rights, for its part, is composed of seven judges elected in a personal capacity. Cases may only be brought before it by a State or the Inter-American Commission on Human Rights after completion of the procedures before that body, when a violation of the Convention by a State is alleged and provided the powers of the Court are recognized by the States in question. Its judgements are final. It makes an annual report on its activities to the Assembly of the OAS, to which it also reports the names of States that have failed to comply with a judgement, since the OAS may be able to settle the problem politically. It is also responsible for giving advice and opinions to the bodies of the Organization of American States or the States themselves on the interpretation of treaties.

#### C. African Commission on Human and Peoples' Rights

52. The African Commission on Human and Peoples' Rights was set up within the Organization of African Unity (OAU) under Article 31 of the African Charter on Human and Peoples' Rights adopted in June 1981. It consists of eleven members 'of the highest reputation, known for their high morality ... and competence in matters of human and peoples' rights' elected for a six-year period by secret ballot by the Assembly of Heads of State and Government of the Organization of African Unity, including those not signatories to the Charter and eligible for re-election. Conversely, the candidates must be nationals of States that have ratified the Charter.

53. The responsibilities of the Commission are to promote rights, interpret the Charter and provide for the protection of human and peoples' rights under the conditions laid down by the Charter and, as necessary, to state its views or make recommendations to governments. It can have recourse to any appropriate form of investigation. Each State Party to the Charter undertakes to produce a report every two years on measures taken to give effect to the rights and freedoms guaranteed by the Charter but nothing is said about the use to be made of these reports or to whom they have to be made (Art. 62).

54. The Commission may be petitioned (Art. 47) by any State Party to the Charter that has 'good reasons' to believe that another State Party to the Charter has violated its provisions. The Commission then, directly or after negotiation, deals with the case with the object of coming to an amicable agreement and drafts a report which it sends to the States concerned and the Assembly of Heads of State and Government to which it may also make recommendations (Art. 52 and 53). The procedure is confidential (Art. 59). Lastly, at each meeting of the Assembly, it submits a report on its activities (Art. 54).

55. Under the terms of Article 55.1, the Commission may also receive other communications, which may - although the Charter does not say so - be from individuals, provided they meet the conditions laid down in Article 56 of the Charter and should it decide by absolute majority of its members to deal with them. The Commission can do no more than draw the attention of the Assembly to such situations. The Assembly can then ask the African Commission on Human and Peoples' Rights to carry out an in-depth study and make a report with recommendations.

56. The confidential procedure limits the petitions' chances of bearing fruit. What is more, only one body, the Assembly of Heads of State and Government, is entitled to make recommendations to settle the problem. The object of the confidentiality clause is that the whole procedure should escape the scrutiny of public opinion, the only power capable of swinging the balance in favour of the protection of human and peoples' rights. The meetings are held behind closed doors and the results cannot therefore be assessed.

#### D. Permanent Arab Commission on Human Rights

57. On 3 September 1968, the Council of the League of Arab States decided to set up a Permanent Arab Commission on Human Rights (Resolution R 2442/48). Like other specialized committees set up previously by the League of Arab States, the Commission is composed of delegates of the Member States. Under its internal rules it takes its decisions by simple majority of the delegates present (Art. 9). The results of its work, in the shape of proposals and agreements (Art. 12), are put before the Council of the Arab League via the General Secretariat of the League.

58. The Commission's activities are at national, regional and world level. Nationally, it encourages the setting up of national commissions on human rights called upon to co-operate with the Commission in joint regional action. Regionally, its task is mainly to co-ordinate national efforts. Lastly, at world level, in addition to its work in favour of international co-operation, it may be required to provide the United Nations Commission on Human Rights - or any other body of that kind - with the information it needs concerning human rights in the Member States of the League.

### III. **Ways in which UNESCO's Standard-Setting Instruments are Monitored**

59. Apart from the procedures for monitoring and implementation of international instruments relating to human rights, it could be interesting to look at the various ways in which the application of certain UNESCO standard-setting instruments is monitored.

#### III.1 **Standard-Setting Instruments of UNESCO**

60. UNESCO is one of the few Specialized Agencies with a substantial standard-setting activity endowed with procedures designed to monitor the standards adopted by the Organization. The diversity of these procedures whereby application of the standard-setting instruments of UNESCO and of the bodies involved in these procedures can be monitored is the price that has to be paid, given the scale of the Organization's standard-setting functions.

61. Unlike the ILO's Constitution, that of UNESCO does not institute any procedure for petitions and complaints regarding non-compliance with the provisions of a ratified convention. It was by special protocol that the Conciliation and Good Offices Commission was set up in the Organization with responsibility for finding solutions to problems arising between States Parties to one of UNESCO's most important conventions, that concerning the prevention of discrimination in the field of education.

62. In general, the procedures for monitoring standard-setting instruments initiated by UNESCO and under its aegis are designed to:

- i) inform States on the way in which the instruments are being applied;
- ii) encourage States to apply these instruments;
- iii) check that they are applied correctly;
- iv) identify any obstacles in the way of their implementation so as to establish whether measures need to be taken by UNESCO to overcome these difficulties.

63. These procedures are defined:

- i) in the Constitution adopted by the General Conference at its fifth session (1950) (Art. IV, par. 4, and VIII);
- ii) in the rules regarding recommendations to Member States and international conventions laid down by Article IV, paragraph 4 of the Constitution, which sets out the procedure for presenting and considering reports from Member States under Articles IV and VIII of the Constitution;
- iii) in UNESCO's standard-setting instruments, some of which make provision for special mechanisms (conventions for the protection of the cultural heritage, 1954 and 1972, Regional Conventions on the Recognition of Studies, Diplomas and Degrees in Higher Education, etc.);
- iv) in the resolutions adopted by the General Conference concerning, firstly, the procedure enabling the application of standard-setting instruments to be monitored (15 C/Res. 12.2) and, secondly, certain specific instruments (Recommendation concerning the Status of Teachers, Declaration on Race and Racial Prejudice, Recommendation concerning Education for International Understanding, Co-operation and Peace and Education relating to Human Rights and Fundamental Freedoms - the monitoring being the responsibility of a consultative committee of experts, the principle of which is laid down in 23 C/Resolution 13.3 and the rules approved by the Executive Board, Revised Recommendation concerning Technical and Vocational Education, etc.).

64. The mechanisms for monitoring UNESCO instruments are of three kinds:

- i) mechanisms for which provision is made in the Constitution;
- ii) implementation mechanisms for which provision is made in conventions;
- iii) implementation mechanisms for which provision is made in specific General Conference resolutions.

65. In general terms, the procedure is as follows:

- i) the special reports sent in by the Member States as laid down in Article IV, paragraph 4 of the Constitution go to the Legal Committee of the General Conference and then to the Conference itself;
- ii) the supplementary reports, the principle of which is provided for under Article VIII of the Constitution and which are called for as required by the General Conference, are considered by the Committee on Conventions and Recommendations and then by the Executive Board in plenary meeting; the report of the CR Committee and the Executive Board's comments are then referred to the General Conference;

- iii) the CR Committee is also the body responsible for the same types of duty in relation to standard-setting instruments containing provisions concerning how their application is to be monitored. In some cases, however, the instrument requires that a specific body be called upon, e.g. the joint ILO/UNESCO Committee, responsible for monitoring implementation of the Recommendation concerning the Status of Teachers and which has to submit its own report to the responsible bodies of the two institutions. In this case, therefore, the sequence is: Joint Committee, Committee on Conventions and Recommendations, Executive Board and General Conference.

66. Conversely, the reports of the States Parties to the Convention for the Protection of Cultural Property in the Event of Armed Conflict (The Hague, 1954) are not one of the CR Committee's responsibilities. Similarly, monitoring the application of the regional conventions on the recognition of higher education studies, diplomas and degrees is that of a specific regional committee in each case. It should be noted that these conventions and that signed at The Hague were not adopted by the General Conference but by international conferences of States.

67. Some conventions, where no reports are called for, also lie outside the competence of the Committee on Conventions and Recommendations. The Convention concerning the Protection of the World Cultural and Natural Heritage (Paris, 1972) and the revised Universal Copyright Convention (Paris, 1971) are illustrations.

68. An interesting example of a specific monitoring mechanism is the Convention for the Protection of Cultural Property in the Event of Armed Conflict (The Hague, 1954). Although the provisions relating to it come under the heading of 'control', the mechanism created by the Convention goes beyond the narrow meaning of monitoring its application. It is dealt with in wide-ranging provisions in the 1954 Convention and its Regulations which, with the protocol, form an integral part of the Convention. In the terms of Article 1 of the Regulations, 'the Director-General of UNESCO shall compile an international list consisting of all persons nominated by the High Contracting Parties as qualified to carry out the functions of Commissioner-General for Cultural Property'. The moment an armed conflict breaks out, a commissioner-general for cultural property is appointed for each State in the conflict by agreement between the government of the country where the commissioner-general is required to perform his/her duties and the protective power of the opposite party. In addition, each belligerent appoints a representative for cultural property located on its territory. The commissioners-general, representatives for cultural property and delegates of the protective powers, are the principal monitoring officials and responsibility for ensuring that the rules of the Convention are complied with is borne by all of them at the different levels. Under Article 8, the Convention also provides for special protection for cultural sites and refuges for cultural property included in the International Register of Cultural Property under Special Protection. Lastly, under Article 26, the High Contracting Parties send a report to the Director-General every four years on the measures taken to ensure the Convention is implemented.

69. Another particular procedure for monitoring the application of standard-setting instruments introduced by UNESCO or framed under its guidance is the use of an intergovernmental committee.

70. Article 8.1 of the Convention concerning the Protection of the World Cultural and Natural Heritage (Paris, 1972), for which UNESCO provides the secretariat, established an intergovernmental committee called the 'World Heritage Committee'. Its members, numbering twenty-one, are elected for a period of six years by a general assembly of the States Parties to the Convention. The election of these members of the committee has to ensure an equitable representation of the different regions (Art. 8.2). Under Article 11 of the Convention a particular responsibility of the World Heritage Committee is to prepare and update the World Heritage List. In its 'Operational Guidelines' for the Convention, this Committee has set out the methods whereby it should carry out its monitoring role over all the property it has decided to include in the World Heritage List. In so doing, it also keeps watch on the compliance of States Parties to the Convention with the undertakings they have entered into. In general the Committee acts on information gathered by its secretariat or by international non-governmental organizations with an advisory status on the Committee.

71. Similarly, Article XI of the Universal Copyright Convention, as revised at Paris on 24 July 1971, provides for the establishment of an intergovernmental committee to administer the Convention known as the 'Intergovernmental Copyright Committee'. The Committee consists of the representatives of eighteen States Parties to the Convention as revised in 1971 or only to the original Convention of 1952. The Committee is selected with due consideration for a 'fair balance of national interests on the basis



of geographical location, population, languages and stage of development'. Bearing in mind Article 1 which defines States' commitment and Article V which, apart from the content of the rights the Convention is concerned with, sets out the restrictions as regards translation rights that States may introduce into their national legislation, the Committee studies problems involved in the Universal Convention's application and functioning. It drafts periodical revisions of the Convention and considers all other problems relating to the international protection of authors' rights in co-operation with international bodies concerned and keeps States Parties to the Convention informed of its activities.

72. As can be seen, the forms that procedures for monitoring obligations accepted by States under the international instruments they have signed and for implementing standard-setting procedures are many and varied. The diversity applies not only to the bodies involved in the procedures and their characteristics, but also to the ways they work and the resources open to them.

### **III.2 Monitoring the Future UNESCO Declaration**

73. The existence of different procedures for protecting human rights shows that in international law, at universal or regional level, there are mechanisms or bodies to monitor the application of these rights by States. In all cases, these mechanisms and bodies are based on international conventions (except for the United Nations Commission on Economic, Social and Cultural Rights and the UNESCO Committee on Conventions and Recommendations). For the moment there are no equivalent mechanisms for monitoring compliance with declarations.

74. In view of the fact that implementation will need to be monitored once the declaration has been adopted, it would be advisable for the International Bioethics Committee of UNESCO (IBC) - whose structures would then need to be changed - to be given this responsibility.

75. The IBC would have to:

- i) encourage the governments of States adopting the declaration to transpose the principles set out in the declaration to their own national legislation, gradually if necessary, or to create the structures they consider appropriate for promoting the principles and rights listed therein (including the principles referred to in the matter of research and the rights with regard to interventions on the human genome);
- ii) commission such studies as they consider useful in the framework of the declaration or as the result of facts that are brought to their notice;
- iii) prepare for the States, as need be, opinions on precise questions concerning the monitoring of action on the declaration;
- iv) provide States with information on measures taken by States in implementation of the declaration; and,
- v) put forward any general observations or recommendations they consider necessary to promote the declaration.

76. In accordance with current practice at UNESCO, this monitoring committee would need to be given a status, yet to be defined, and rules of procedure laying down the way in which it would operate. As regards the rules of procedure, the major issue of who would have the right to present a case to the committee would need to be settled in the light of the various alternatives possible: States, international intergovernmental and non-governmental organizations that have relations with UNESCO, and private individuals or groups of persons closely involved with the facts brought to the notice of the committee. Furthermore, as regards working methods, it would be advisable to refer to current experience in the IBC, where discussions take place in the greatest freedom.

77. The composition of the committee should reflect not only the regional and cultural diversity that bioethics questions should cover but also the pluridisciplinarity of the subject. While membership of the committee should, of course, be open to representatives of the States, considerable space should nevertheless be allowed for representatives of the scientific world. That having been said, the fullest flexibility should be ensured, since bioethics is a fast-growing field. Constant momentum would need to be maintained between government and scientific representatives while possible political differences should be kept to a minimum in a context guaranteeing the utmost freedom of expression. A certain balance therefore needs to be sought in the composition of the committee.

78. The momentum could be achieved, for example, by having a bi-partite committee with an appointment procedure ensuring equality on either side. It could be the responsibility of the General Conference to appoint the representatives of the States and that of the Director-General to select the representatives of the scientific world. It would also be important to make sure that each State should not be represented on the committee by more than two persons. Lastly, in order to secure the mobility desired, half of the committee members should be re-appointed every four years. When the committee was first set up, lots would be drawn to select that half of the membership that would sit on the committee for only two years.

79. While the usual advantages of a body made up of independent experts are well known, especially where the body is responsible for comparing measures taken individually by each State with a set of general rules, in this case an intergovernmental unit coupled with a membership appointed in the right way (obeying the twofold criterion of individual competence in every case and representation of the varied scientific, political and social fields) would be preferable. It would ensure that decisions met relevant criteria and also that the States, being represented on the committee, would be effectively committed to monitoring compliance with the declaration.

80. A pattern of categories emerges from an analysis of the monitoring mechanisms and procedures of standard-setting instruments referred to in this paper. In the following list it is used to classify the bodies with whom the implementation of the legal instruments is entrusted.

- i) *Intergovernmental bodies brought into being by international conventions (universal or regional)*
  - Committee against Torture,
  - Committee on the Rights of the Child,
  - Human Rights Committee,
  - Intergovernmental Copyright Committee,
  - World Heritage Committee,
  - Committee on the Elimination of Discrimination against Women,
  - Committee on the Elimination of Racial Discrimination,
  - Regional Committees (for the application of the Regional Conventions on the Recognition of Studies, Diplomas and Degrees in Higher Education entered into under the aegis of UNESCO),
  - African Commission on Human and Peoples' Rights,
  - European Commission and Court of Human Rights,
  - Inter-American Commission and Court on Human Rights.
- ii) *Bodies set up by the legislative organs of the United Nations system responsible for the implementation of conventions or the monitoring of questions concerning the promotion of human rights*
  - Conciliation and Good Offices Commission responsible for seeking the settlement of any disputes which may arise in the implementation of the Convention against Discrimination in Education adopted by the General Conference of UNESCO in 1960, which is the subject of special monitoring arrangements under a protocol adopted in 1962,
  - United Nations Commission on Human Rights (and Sub-Commission on Prevention of Discrimination and Protection of Minorities),
  - United Nations Commission on Economic, Social and Cultural Rights.
- iii) *Bodies in the organizations of the United Nations system responsible for the implementation of standard-setting instruments (whether conventions or otherwise)*
  - ILO Fact-finding and Conciliation Commission,
  - UNESCO Committee on Conventions and Recommendations (CR Committee),
  - Commission of Experts for the Application of ILO Conventions and Recommendations,
  - ILO Committee on Freedom of Association.

- iv) *Ad hoc mechanisms responsible for the implementation of standard-setting instruments (in the form of conventions or otherwise)*
- Consultative Committee of Experts for the implementation of the UNESCO Recommendation concerning Education for International Understanding, Co-operation and Peace and Education relating to Human Rights and Fundamental Freedoms, the principle of which is enshrined in 23 C/Resolution 13.3 and the statutes approved by the Executive Board,
  - Joint ILO/UNESCO Committee of Experts on the Application of the Recommendation concerning the Status of Teachers,
  - Commissioners-General responsible for ensuring compliance with the provisions of the UNESCO Convention for the Protection of Cultural Property in the Event of Armed Conflict (The Hague, 1954).

81. No declaration adopted by the Member States of UNESCO has yet been followed by the institution of monitoring machinery. One particular case, however, needs mentioning - that of the Declaration on Race and Racial Prejudice, adopted by the General Conference on 27 November 1978. When adopting this declaration, the General Conference, in 20 C/Resolution 3/1.1/3, also invited the Director-General to prepare a comprehensive report on the world situation in the fields covered by the declaration on the basis of information supplied by Member States. In the same resolution it also invited the Director-General to submit to it any comments and recommendations deemed necessary to promote the implementation of the declaration.

#### **IV. Proposals for Monitoring Compliance with the Future Declaration**

82. Notwithstanding the above and by way of illustration, five possibilities could be considered for the composition of the restructured IBC. The members of the IBC could:

- i) serve in a personal capacity by virtue of their recognized competence in the fields covered by the declaration; they would be appointed by the Director-General with due heed to equitable geographical representation;
- ii) serve in a personal capacity by virtue of their recognized competence in the fields covered by the declaration; they would be elected by the General Conference on the basis of applications submitted by the Member States of UNESCO;
- iii) be elected by the General Conference on the basis of a list proposed by the Director-General meeting the criteria set out under (i) above;
- iv) represent the Member States of UNESCO elected by the General Conference at its ordinary meetings, bearing in mind the need for equitable geographical representation. The States elected would be invited to appoint persons with recognized competence in the fields covered by the declaration; or,
- v) be, for half their number, representatives of Member States elected by the General Conference, and half persons appointed by the Director-General acting in a personal capacity and meeting the above criteria.

Whatever the option chosen, the IBC could not include more than two nationals from any one State.

83. Under the last of the above options, therefore, the IBC would have a balanced bi-partite structure totalling twelve representatives of Member States of UNESCO who could be elected in the light of the need to ensure a fair geographical distribution and appropriate rotation, and of the depth of their commitment to the declaration. Their term of office could be four years from the end of the ordinary session of the General Conference during which they were elected to the end of the second ordinary meeting thereafter. The Member States of the IBC would be eligible for re-election only once. The committee for monitoring compliance with the declaration would be assisted by scientific advisers appointed by the Director-General in accordance with the criteria set out in the following paragraph and of whom there would also be twelve.

84. Under the various options, all UNESCO Member States and Associate Members not members of the committee would have observer status at the committee's meetings. In accordance with current practice, representatives of the Organization of the United Nations and other United Nations organizations could be invited to the meetings of the committee, likewise with observer status. Lastly, the committee would specify the conditions in which other international governmental or non-governmental organizations could be invited to attend the proceedings and the committee would also have the right to lay down the conditions in which certain specialists could be consulted in matters within their field.

## V. Conclusion

85. The Legal Commission is required to decide on the proposals for monitoring compliance with the future declaration on the human genome and human rights which are to be submitted to the UNESCO International Bioethics Committee for consideration. Proposed statutes will then be drafted in the light of the latter's recommendations. A second draft resolution, regarding the implementation and monitoring of the declaration and including the proposed statutes, will also be submitted to the General Conference for adoption at its twenty-ninth session.

## BIBLIOGRAPHY

- ALBANESE, S. *Promoción y protección internacional de los derechos humanos*. Buenos Aires: La Rocca, 1992
- ALSTON, PH. (eds), *The United Nations and Human Rights. A Critical Appraisal*. Oxford: Clarendon Press, 1992
- ARDANT, PH. *Les textes sur les droits de l'homme*, 2nd edition. Paris: Presses universitaires de France, 1993
- BADAWI EL-SHEIKH, I.A. *International Implementation of the International Covenants of Human Rights*. Cairo: Cairo Univ., 1984
- BEDJAQUI, M. (ed.), *Droit international: bilan et perspectives*, Vol. I and II. Paris: Pédone/UNESCO, 1991 (see more particularly Vol.II)
- BENNOUNA, M. *Droit international du développement*. Paris: Berger Levrault, 1983
- BERNHARDT, R. AND JOLOWICZ, J.A. (eds), *International Enforcement of Human Rights*. Berlin/New York: Springer, 1987
- BROWNLIE, I. *Basic Documents on Human Rights*, 3rd edition. Oxford: Clarendon Press, 1994
- BUERGENTHAL, TH.; NORRIS, R. AND SHELTON, D. *La protección de los derechos humanos en las Américas*. Madrid: Civitas, 1990
- BUERGENTHAL, TH. AND KISS, A. *La protection internationale des droits de l'homme*. Kehl/Strasbourg/Arlington: Engel, 1991
- BUERGENTHAL, TH. *International Human Rights in a Nutshell*. Saint Paul (Minn.): West Publishing Company, 1988
- CANÇADO TRINIDADE, A.A. *A proteção internacional dos direitos humanos*. Rio de Janeiro: Destaque Editora, 1988
- CANÇADO TRINIDADE, A.A. *La protección internacional de los derechos humanos en América Latina y el Caribe*. San José: IIDH, 1993
- CASSESE, A. *Los derechos humanos en el mundo contemporáneo*. Barcelona: Ariel, 1992
- COT, J.-P. AND PELLET, A. (eds.), *La Charte des Nations Unies - Commentaire article par article*. Brussels: Economica, Bruylant, 1995
- DUMONT, G.-H. Une action concrète de l'UNESCO en matière de droits de l'homme. *Revue internationale des sciences sociales*, vol. XLI, Paris, 1989

- DUPUY, P.-M. *Grands textes de droit international public*. Paris: Dalloz, 1996
- ERMACORA, F.; NOWAK, M. AND TRETTER, H. *International Human Rights: Documents and Introductory Notes*. Vienna: Law Book in Europe, 1993
- FRIEDMANN, J.R. AND SHERMAN, I.M. *Human Rights. An International and Comparative Law Bibliography*. Syracuse: Greenwood Press, 1985
- GROS ESPIELL, H. *Estudios sobre los Derechos Humanos*. Vol. I. San José/Caracas: IIDH/Editorial Jurídica Venezolana, 1985; Vol. II. San José/Madrid: IIDH/Editorial Civiles, 1988
- GROS ESPIELL, H. *Derechos Humanos y Vida Internacional*. Mexico: UNAM/Comisión Nacional de Derechos Humanos, 1995
- GROS ESPIELL, H. *Derechos Humanos*. Lima: Editorial Cuzco, 1991
- GROS ESPIELL, H. *La Convención Europea y la Convención Americana de Derechos Humanos: Análisis comparativo*. Santiago del Chile: Editorial Andrés Bello, 1992
- GROS ESPIELL, H. La Convention américaine et la Convention européenne des droits de l'homme: analyse comparative. *Recueil des cours de l'Académie de droit international*, La Haye, T. 218, 1989-VI
- GROS ESPIELL, H. *Los derechos económicos, sociales y culturales en el sistema interamericano*. San José: Asoc. Libro Libre, 1986
- HAMALENGWA, M.; FLINTERMAN, C. AND DANKWA, E.V.O. (eds.), *The International Law of Human Rights in Africa: Basic Documents and Annotated Bibliography*. Dordrecht/Boston: Nijhoff, 1988
- HANNUM, H. (ed.), *Guide to International Human Rights Practice*, 2nd edition. Philadelphia: Univ. of Penn. Press, 1992
- HENKIN, L. AND HARGROVE, J.L. (eds.), *Human rights: An Agenda for the Next Century*. Washington: ASIL, 1994
- HUMPHREY, J. *No Distant Millennium. The International Law of Human Rights*. Paris: UNESCO, 1989
- M'BAYE, K. Le droit au développement comme un droit de l'homme. *Revue des droits de l'homme*, vol. V, N° 2-3, Paris, 1972
- M'BAYE, K. *Les droits de l'homme, demain* (Conférence solennelle d'introduction à la 25e session d'enseignement de l'Institut international des droits de l'homme (IIDH), 4 July 1994). Strasbourg: IIDH, 1994
- M'BAYE, K. *Les droits de l'homme en Afrique*. Paris: Pédone, 1992
- MADIOT, Y. *Droits de l'homme et libertés publiques*. Paris: Masson, 1976
- MATHIEU, J.-L. *La défense internationale des droits de l'homme*. Paris: Presses universitaires de France, 1993
- NGUYEN, Q.D.; DAILLIER, P. AND PELLET, A. *Droit international public*, 3rd edition. Paris: Librairie générale de droit et de jurisprudence, 1987
- PARTSCH, K.J. La mise en oeuvre des droits de l'homme par l'UNESCO, remarques sur un système particulier. *Annuaire français de droit international*, XXXVI, Paris: Editions du CNRS, 1990
- PECES-BARBA MARTINEZ, G. (ed.), *Derecho positivo de los derechos humanos*. Madrid: Debate, 1987
- PRÉMONT, D. AND MONTANT, F. (eds.), *Le droit à la vie quarante ans après l'adoption de la Déclaration universelle des droits de l'homme: évolution conceptuelle, normative et jurisprudentielle*. Geneva: Assoc. CID, 1992
- ROLLAND, P. AND TAVERNIER, P. *Textes sur la protection internationale des droits de l'homme*, 2nd edition. Paris: Presses universitaires de France, 1989
- SIEGHART, P. *The International Law of Human Rights*. Oxford: Clarendon Press, 1983

- SUBRAMANYA, T.R. (ed.), *Human Rights in International Law*. New Delhi: Deep and Deep Pub., 1986
- UNESCO. *Conventions and Recommendations of UNESCO concerning the protection of the cultural heritage*. Paris: UNESCO, 1987
- UNESCO. *Human Rights: Major International Instruments*. Paris: UNESCO, 1995
- UNESCO. *UNESCO's Standard-setting Instruments-revised edition*. Paris: UNESCO, 1993
- VASAK, K. (ed.), *The International Dimension of Human Rights*. Paris: UNESCO, 1978
- VILLAN DURAN, C. *Curso de derecho internacional de los derechos humanos*. Strasbourg: Institut international des droits de l'homme, 1996
- VILLAN DURAN, C. La protección de los derechos humanos en el sistema de las Naciones Unidas. *Jueces para la democracia*, 24 November 1995
- ZWAAK, L.F. *International Human Rights Procedures: Petitioning the ECHR, CCPR and CERD*. Nijmegen: Ars Aequi, 1991

# SEVENTH MEETING OF THE LEGAL COMMISSION OF THE IBC

(Paris, 3-4 October 1996)

## I. Introduction

The seventh meeting of the Legal Commission of the International Bioethics Committee of UNESCO (IBC) was held in Paris on 3 October 1996. Its purpose, in particular, was to examine the 'Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights' of 4 March 1996<sup>(28)</sup>. This preliminary draft takes into account the proposals made at the fifth meeting of the Legal Commission (25 September 1995), the third Session of the IBC (27 and 29 September 1995) and the sixth meeting of the Legal Commission (25 January 1996) as well as the findings of the international consultation undertaken between May 1995 and January 1996. The seventh meeting of the Commission also examined the text outlining a mechanism for the monitoring of the future universal declaration.

The file distributed to each participant contained in particular observations presented by Mr Ernst Benda and the Honorable Judge Michael Kirby, both members of the Legal Commission of the IBC.

The present report refers to comments made during the seventh meeting of the Legal Commission on 3 October as well as during the discussions of the IBC on the 'Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights', in plenary session on 4 October 1996.

Mrs Noëlle Lenoir, Chairperson of the IBC, welcomed all those present, especially the new members of the IBC, and recalled the mandate given to the IBC by the Director-General of UNESCO, under the resolution adopted by the General Conference of UNESCO in 1995 (28 C/Res. 2.2). The Chairperson of the IBC recalled that the preliminary draft was the result of discussions in the IBC and that, at this stage, it had not yet been examined by the Member States. Mrs Lenoir stated that, at its 150th Session (October 1996), the Executive Board of UNESCO was supposed to decide on invitations to the meeting of the committee of governmental experts for the finalization of a declaration on the human genome (document 150 EX/34). This committee would meet in 1997 and finalize the project to be submitted to the twenty-ninth Session of the General Conference in October-November 1997.

She reminded the participants that, in addition to its multidisciplinary nature, the composition of the International Bioethics Committee reflects the plurality of present currents of opinion, and that this is what gives the IBC its richness. She stressed the fact that the IBC has carried out its work freely for its members are independent and have been appointed *intuitu personae*. However, this does not negate the political weight given to it by the fact that the General Conference has approved the broad lines of the preliminary draft of the universal declaration. This document will be far-reaching as it will be the first international text to bring the question of human dignity face to face with the problems raised by scientific progress. Citing observations made by the new members of the Legal Commission, she

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28. See Annex VIII.

stressed the fact that the proposed text must be universal and intercultural in its scope and that it be placed at a level that excludes any reference to specific scientific or therapeutic practices that might exist in some States. The preliminary draft is a reference text asserting principles that are the result of collective work by and dialogue amongst scientists, jurists and philosophers.

She said that the Director-General would be forwarding the conclusions of the IBC for comment to the Member States of UNESCO. She stressed the fact that the preliminary draft, as part of the IBC's own dynamics, needs a pragmatic dimension. This explains the proposal for a mechanism to monitor the future universal declaration, prepared by His Ex. Mr Héctor Gros Espiell, Chairman of the Legal Commission of the IBC.

## **II. Presentation of the Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights**

Mr Mohammed Bedjaoui, President of the International Court of Justice (ICJ), recalled the institutional framework of the preliminary draft as well as the initial steps leading to the text being submitted for examination by the Legal Commission of the IBC. He cited the reasons for the choice of the declarative form for the elaboration of a universal text on the human genome, without prejudice to the possibility of subsequently preparing a multilateral universal convention. In this respect, he recalled the United Nations doctrine according to which 'a declaration is a formal and solemn instrument that is justified on infrequent occasions when principles of major importance and lasting validity are being stated ..., with stress laid on moral authority'.

He stressed the fact the goals and principles spelled out in the text were designed to encourage genetic research and orient its development for the benefit of humanity with full respect for human rights in accordance with the threefold principle of the dignity of the human person, freedom of research and human solidarity. He then put forward his reflections on certain aspects which, in his view, needed clarification before the final revisions that might be deemed necessary by the Commission. He pointed out that the comments accompanying each article of the preliminary draft identify its problematics and the issues at stake in keeping with a practice commonly followed in the United Nations and in international law.

In placing the human genome and human rights along side each other in the title, the IBC, in a constructive approach, has sought to cover all of humanity's genetic material and all the characteristics of a person. The rights of the person have already been specified in many international texts. Here, it is in relation to genetic research and its implications for these rights (which are, besides, intangible). It might be appropriate to reflect further on the title and possibly reword it.

With regard to the Preamble, the seven preambular paragraphs present a satisfactory balance in stating the references and the aspirations that the text responds to as a whole. However, the fourth preambular paragraph, relating to biological diversity as a source of wealth for humanity, might need to be reinforced. The warning against any interpretation running counter to the equal dignity of human beings is of increasing importance today in a context of the ever-possible resurgence of theories with racial connotations.

The President of the ICJ acknowledged the 'revolutionary' character, in the symbolic sense of the term, of the last sentence in the preamble proclaiming the human genome as 'common heritage of humanity'. All the articles are derived from the innovative character of this expression from which it is certain that numerous conclusions will be drawn in the future as and when progress is made in genetics. This is a key phrase that needs to be incorporated into Article 1 of the preliminary draft declaration and hence enshrined in the title-page of the future declaration. Furthermore, the notion of a 'fundamental component of the common heritage of humanity' which occurs in the said article may appear to be weak. The human genome should be considered as common heritage in its entirety, in the same way as the celestial bodies, the seabed or certain forms of natural, but above all, cultural heritage. He felt it might seem that, in its present formulation, this latter notion had been evoked in a furtive manner. On the contrary, it needs to be given greater value by being 'entwined' into the wording of Article 1. The notion of the genome as common heritage of humanity could be affirmed if, apart from the preamble, the text consisted of only two articles. Article 1 would proclaim the human genome as common heritage of humanity, while Article 2 would stipulate the adoption of the declaration by the States, the remainder of the operative part stating the principles to be complied with would be placed as an annex.



### **III. Presentation of the Mechanism for Monitoring the Future Declaration on the Human Genome and Human Rights**

H. Ex. Mr Héctor Gros Espiell, Chairman of the Legal Commission of the IBC, stressed that the text submitted for examination by the Commission was the result of three years' work by this Commission and that it had gathered the views of many ethics committees and scientific, university and legal institutions.

The Chairman of the Legal Commission recalled that, in its 28 C/Resolution 0.12, on the Medium-Term Strategy of the Organization, unanimously adopted in 1995, the General Conference of UNESCO had in fact qualified the human genome as common heritage. Indeed, in paragraph 6 of the provisions of this resolution, the General Conference:

Reaffirms, in this respect, the urgent need to strengthen the moral solidarity of mankind in order to safeguard its common heritage - natural and cultural, tangible and intangible, intellectual and genetic.

He agreed with the President of the ICJ on the need to reinforce the fourth preambular paragraph which is an essential element in a context where it is necessary to emphasize the struggle against racism and discrimination. He too pointed out that the text being dealt with was a declaration and not a convention, but that in any case it appeared to be indispensable to provide for a mechanism to monitor its implementation. As for the question of whether it is appropriate to keep the expression 'the States shall undertake' mentioned by Mr Bedjaoui, he felt that, in view of the current development of international law, this wording seems possible, all the more so as principles already existing in international law are being reaffirmed here. He felt that the innovative idea of an undertaking by States, in a declarative text, is an acceptable one. Referring to this idea could give particular force to the declaration once adopted. Thus, in addition to its moral force, it will acquire legal force without becoming binding in any way. It will perhaps become a source of law, an idea underlying the section relating to its implementation.

## **IV. General Discussion**

### **A. *The Human Genome, Common Heritage of Humanity***

In an examination of the last two lines of the Preamble and of Article 1, the Commission discussed the qualification of the human genome as common heritage of humanity. Several members, agreeing with the President of the ICJ, felt that it was indispensable to reinforce it by incorporating it in the preliminary draft as an Article 1. Some members also felt that the juxtaposition of the terms 'proclaims' and 'adopts', in the last sentence of the Preamble was not appropriate. These two notions deserve to be dealt with separately, and the incorporation in Article 1 of the definition of the human genome as 'common heritage of humanity' would respond to this observation.

Several speakers pointed out the ambiguities in the definition of the human genome as an essential component of the common heritage of humanity. Some felt that, in scientific terms, more than 90% of the human genome was common with that of other species. Others felt that, legally speaking, the notion of a common heritage could create tension between the individual heritage of a person and the heritage of the species, for each gene is thus deemed to be the property of an individual and an inalienable property of humanity. A member of the Commission stressed the fact that the common heritage of humanity appeared here as a subject of law. Several speakers felt it necessary to consider the specific legal consequences of the adoption of such a notion, especially with regard to issues relating to patentability. Others acknowledged that the notion of common heritage had a symbolic character that it was essential to maintain in the declaration. Indeed, it was necessary to refer to values to be preserved and not to objects. A member of the Commission recalled that the notion of common heritage of humanity henceforth formed part of the tradition of public international law and that the concept of dignity was not strong enough to provide a mandate for international control. The reference to the common heritage in the field of genetics therefore appeared to him to be indispensable in order to emphasize the importance of safeguarding the integrity of the species through the protection of the human genome.

A member of the Commission pointed out that the genetic information contained in the genome represented a resource and that, on this basis, the right to its possible exploitation should, in the common interest, belong to the international community as a whole. He pointed out that, depending on the specific case being considered, the genome could be a subject as well as an object of law and wondered whether the time had not come to envisage the setting up of a third legal order where the subject of law would be also an object of law. Certain speakers recalled that it is perhaps possible to make a distinction in the genome between the object and the value, and that the inalienable ownership of the object in no way precludes the adoption of provisions favourable to its exploitation, provided that it is done in the interest of humanity as a whole.

Two speakers felt that the notion of the human genome, considered as belonging to the common heritage of humanity, needed to be developed so as to be gradually integrated into the different cultures, as well as into legal instruments, as had been done in other fields also qualified as common heritage. They stressed the fact that human dignity is the cardinal principle of the text. One speaker, considering this question to be an essential and fundamental one, questioned the reasons underlying the introduction of this notion and wondered if it were not aimed at preventing any possible appropriation, for purposes of exploitation, of the human genome or at avoiding any debate on patentability. He felt that only research on the genome could be considered as belonging to the common heritage of humanity<sup>(29)</sup>.

Several speakers however felt that it was desirable to keep the current form of presentation. Given the discussions on the concept of common heritage, going any further with the wording might be detrimental to the entire text. Furthermore, if there had to be a modification, it should bring out the fact that the notion of the common heritage of humanity is at the heart of the debate on the human genome. Others wished that a definition of the genome should be inserted. In this respect, a member of the IBC pointed out that it would be probably more accurate in scientific terms to make a distinction between operations on somatic cells and operations affecting germ cells. This distinction appeared to be essential to some participants, especially given the possibility of germline gene therapy. A new member of the Legal Commission congratulated the Commission for the work already accomplished and stressed the fact that it would be vain to try and make a legal mode of reasoning coincide in an absolute way with the scientific mode of reasoning. He felt that the text presented was a good start and gave it his unreserved support.

Inasmuch as the declaration tended to bring out general principles applicable to singular (technical and cultural) situations, several speakers felt that the reference to particular forms of therapeutic action could implicate the declaration in considerations falling within the preview of States and thus get involved in debates at a national level. Besides, since the practices are not always universal, it would seem desirable to use a wording likely to gain international consensus. The members of the Commission hoped that a formulation enabling the genome to be considered in its totality would be adopted.

## **B. Article by Article Examination**

### **i) Title**

Apart from the considerations spelled out in Section II of the present report, one member of the Commission found the title to be lacking in specific character and felt that it might be appropriate to modify it in order to state that it is a 'declaration of principle'. The Commission did not accept this suggestion, as the purpose of the declaration is to state principles.

### **ii) Preamble**

#### **FIRST PREAMBULAR PARAGRAPH**

One member of the Legal Commission asked that the Universal Declaration of Human Rights and the International Covenants should be mentioned in this preambular paragraph and should prevail over UNESCO's Constitution. In this respect, it must be pointed out that in keeping with the

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29. In this respect, it may be useful to refer to the Convention concerning the Protection of the World Cultural and Natural Heritage (Paris, 16 November 1972). The fact that specific properties belong to the World Heritage in no way weakens the sovereignty of States over the territories in which the said properties are situated (Art. 6), nor a free use of the resources that these properties may induce.

chronology of the texts, UNESCO's Constitution, adopted on 16 November 1945, should be mentioned at the beginning of the Preamble. Furthermore, it is logical that a normative text emanating from UNESCO should refer in the first place to its Constitution.

#### SECOND PREAMBULAR PARAGRAPH

It was proposed that the expression 'biological' used to specify the nature of the bacteriological weapons cited be replaced by 'prohibited weapons'. Since the expression in question is an integral part of an international convention, it cannot be replaced by another term.

#### THIRD PREAMBULAR PARAGRAPH

One member of the Commission suggested the addition of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization (WTO), entered into force on 1st January 1995, in the list of international texts pertaining to the protection of intellectual property.

#### FOURTH PREAMBULAR PARAGRAPH

Some speakers pointed out that human genetic diversity in no way questioned the principle of the dignity of each individual which is the cardinal principle of the declaration. It was specified that the reference to this principle in the text is designed essentially to serve as a political and moral signal so that its assertion may not give rise to liberticide interpretations. Several speakers pointed out that it would be desirable to make express mention of genetic diversity as a source of wealth for humanity. Other speakers recalled that the declaration will confirm the biological unity of the human species that underlies genetic diversity.

#### SIXTH PREAMBULAR PARAGRAPH

Several participants asked that the four sub-paragraphs of this preambular paragraph be incorporated into the operative part of the declaration, in Section B on 'Research on the Human Genome'. Due to the operational character of these paragraphs, this would give them greater importance. Furthermore, one member of the Legal Commission wished that the wording 'for eugenic ends' be added to the end of sub-paragraph (c).

#### LAST SENTENCE OF THE PREAMBLE

Several members of the Legal Commission supported the suggestion to incorporate this sentence into the operative part of the declaration in the form of a new Article 1 or of inserting it into the present Article 1. While taking account of considerations already spelled out on this point, one speaker wished that the wording of the proclamation should read as follows: 'proclaims the principles set forth by ...'.

### iii) Section A - The Human Genome

#### ARTICLE 1

The comments and suggestions made on this article are already contained in Sub-section A of the present report entitled 'The Human Genome, Common Heritage of Humanity'. One member of the IBC suggested that, with a view to a clearer understanding, the observations on this article, in the presentation of the Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights should be inserted as a footnote in the text. Another, supporting certain comments according to which the genome, since it gives an individual his 'genetic identity', cannot be considered part of the common heritage of humanity, suggested that this article be amended to incorporate the notion of 'genetic identity' contained in Article 2 (a).

#### ARTICLE 2 (B)

To give greater force to this article, one member of the IBC wished that the expression 'should not' replace the term used 'cannot'. He also felt that the identity of an individual cannot be reduced to the genetic aspect and also suggested that the term 'an individual's personality' be modified.

iv) Section B - Research on the Human Genome

ARTICLE 5

Several members of the Legal Commission declared that it would be appropriate, in general, to specify that all scientific progress should be achieved with full respect for human dignity. Some even wished to see the addition of the point that research in genetics should be exploited for peaceful purposes. One speaker stressed the importance of the applications flowing from the direct consequences likely to arise from the notion of a common heritage. Furthermore, certain speakers wished that the need for a sharing of the results of research between the countries of the North and those of the South be mentioned. One speaker suggested that the expression 'safeguard the polymorphic integrity of the human species' be included in order to prevent any misunderstanding about the diversity referred to. Several speakers felt that, since Article 4 referred to the biological unity of humankind, in no way was there any question of diversity serving as a basis for racist arguments but that in any case this article did not tend to minimize the importance of biodiversity. One member of the Commission suggested that this article be inserted at the beginning of the text.

ARTICLE 5 (A)

Some speakers felt that the definition of research as given, namely an 'essential activity of the mind' was not entirely satisfactory. Also, one member of the Commission felt that this article should be given greater force in specifying firstly that safeguarding the integrity of the species is an essential application of the notion of common heritage and secondly that 'research should contribute to the progress of knowledge'; He did not believe that incidental insertions were sufficient. One member of the Commission proposed a new wording for this sub-paragraph to introduce limits to the applications of research. According to him, the reference to the vocation of research, as a source of progress, knowledge and the improvement of humankind's well-being was not a sufficient guarantee against possible deviations, especially eugenic.

ARTICLE 5 (B)

Freedom of research was affirmed as the right of the individual. However, several members of the Commission felt that its results should not be the object of appropriation by States or by particular groups. This affirmation appeared to justify the fact that the question of the patentability of the genome is not referred to in the preliminary draft. Some, on the contrary, felt that the results of research should be the object of intellectual protection.

ARTICLE 6

One member of the Commission wanted emphasis to be placed on respect for the dignity of the person in specifying that 'every scientific advance take place with due respect to human dignity'.

v) Section C - Interventions Affecting the Human Genome

ARTICLE 7

The wording of this article raised several questions. Certain members of the IBC felt that, if this article were to be interpreted to the letter, it would not be possible to carry out certain operations such as blood transfusions after accidents. The notion of prior consent mentioned therefore needs to be qualified.

ARTICLE 8

One member of the IBC felt that the importance of this article justified its being placed at the beginning of the text in the form of a new Article 1.

ARTICLE 9

Several members of the Commission stressed the importance of the confidentiality of genetic data. Some however suggested the insertion of a clause to permit the lifting of this confidentiality in the event of exceptional circumstances, especially with regard to information on infants. Other members on

the contrary felt that the principle of protecting the confidentiality of genetic data associated with a named person from third parties had to be absolutely maintained in order to prevent abuses and avoid repeated exceptions. For certain members of the Commission, the scope of the concept deserved in any case to be further explored.

#### ARTICLE 10

One member of the Legal Commission, referring to the notion of reparation dealt with by this article, felt that its implementation could raise problems of the application of civil law because of the notion of damages attached to it. Considering that each jurisdiction is free to decide on the question of damages, he wished that the declaration should not mention this subject. The question of the rights of descendants with respect to civil liability was mentioned but did not receive any favourable response from the members of the Legal Commission. One of them, referring in particular to 'direct' causes of damages, rejected the inclusion of clauses entailing responsibility between generations, to avoid a situation where descendants might invoke such clauses to claim reparation.

#### vi) Section D - Rights and Obligations of Researchers

##### ARTICLES 11 AND 12

In Article 11, the expression 'States encourage ...' was preferred to the expression 'States shall ensure ...'. Article 12 for its part did not give rise to any particular comments.

##### ARTICLE 13

One member of the IBC felt that, above all, this article should stress the responsibility of researchers in questions related to conflict of interest and duty.

#### vii) Section E - Duties and Responsibilities Towards Others

##### ARTICLE 14

The notion of the 'duty of solidarity' drew the attention of participants, some feeling that it lacked clarity, especially in English. Several speakers felt that the 'guarantee of the effectiveness of the duty of solidarity' on the part of States was difficult to conceive in terms of implementation.

#### viii) Section F - International Co-operation

##### ARTICLE 16

Within the framework of international co-operation, several speakers suggested the addition of a clause stipulating that the results of research and the benefits resulting therefrom should be shared with the developing countries.

##### ARTICLE 17

The term 'promote' was deemed to be weak by some members whilst others wanted a more binding wording to be used. Furthermore, some members of the Commission wished that the implications of biology and genetics on the environment should be mentioned.

##### ARTICLE 18

Several members of the IBC stressed the importance of education in bioethics. It was felt that the educational aspects should be taken into account in the declaration and affirmed by the addition of a new sub-paragraph by virtue of which the States would have to ensure education in bioethics within their societies.

ix) **Section G - Implementation of the Declaration**

ARTICLES 19 TO 21

In general, the majority of the members of the Legal Commission were favourable to the setting up of a mechanism to monitor the declaration. The importance of such a text, considered to be fundamental, justifies the binding wording used in this section. One member of the Commission referred to the precedent of the Universal Declaration of Human Rights which has now become an integral part of international common law. Some speakers however questioned the validity of the comminatory language sometimes used and pointed out that a declaration usually establishes neither duties nor obligations. Inasmuch, as no sanction had been provided for in the event of non-observance by States with the commitments set forth in the text, one speaker suggested that the text be reinforced by indicating concrete steps that States could adopt. Other speakers, with a view to ensuring that the declaration would obtain the consensus of the community of States, suggested that the expression 'undertake to ensure that the principles set out in this Declaration are respected' in Article 19 be replaced by 'undertake to promote that the principles ... are respected'. Furthermore, some members of the Commission felt that it would be appropriate, in the context of the monitoring of the declaration, to envisage assistance for the establishment of national ethics committees and the drafting of legislation.

ARTICLE 22

One speaker suggested that this article should be reworded to refer to the promotion of the declaration as an obligation of the International Bioethics Committee.

**C. *Mechanism for Monitoring the Declaration***

The mechanism for monitoring the future universal declaration on the human genome and human rights outlined by the Chairman of the Legal Commission met with the approval of the members of this Commission. They hailed the originality and innovative character of the proposal whilst at the same time wondering how the relevant information could be collected, inasmuch as no obligation is laid down for the States. In order to give the declaration greater impact on realities, the speakers on this point wished that the monitoring mechanism should be matched with concrete measures. Indeed, several speakers stressed the fact that the declaration would have no real impact except by the setting up of the monitoring committee as referred to in this document. Two members of the Commission wished that, at a forthcoming meeting, provision be made for a discussion on the working methods of this monitoring committee.

**V. Conclusions**

Following the discussions of the International Bioethics Committee, and in the light of the observations presented during the meeting of the Legal Commission, the text of the 'Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights' in its broad lines was approved in plenary session. The IBC entrusted its Legal Commission with the finalization of the text for transmission to the Member States of UNESCO, prior to the meeting of the committee of governmental experts for the finalization of a declaration on the human genome.

In keeping with the wishes expressed by several members of the Legal Commission, it was decided that, at the end of the work of the Legal Commission, the finalized text would be accompanied by an article by article presentation of the preliminary draft.

Mrs Lenoir, Chairperson of the IBC, thanked the Chairman of the Legal Commission, the members of the Legal Commission and the members of the IBC for their contribution, and recalled the timetable of future discussions up to the forwarding of the preliminary draft to the Member States of UNESCO. She informed the assembly of the forthcoming meeting of the Legal Commission on 16 and 17 December 1996.

# **EIGHTH MEETING OF THE LEGAL COMMISSION OF THE IBC**

(Paris, 16-17 December 1996)

## **I. Introduction**

The fourth Session of the International Bioethics Committee of UNESCO (IBC) (3-4 October 1996) approved the general outline and main features of the 'Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights'. The IBC further entrusted its Legal Commission with finalizing the text on the basis of the observations made at the Commission's seventh meeting and by itself in plenary. The eighth meeting of the IBC Legal Commission, extended to IBC members wishing to assist in finalizing the preliminary draft, was therefore held in Paris on 16 and 17 December 1996.

The file given to all participants included a provisional version of the revised preliminary draft of a universal declaration on the human genome and human rights<sup>(30)</sup> and the report of the seventh meeting of the Legal Commission.

Several information documents were made available to participants, including a note on the deliberations of the 150th Session of UNESCO's Executive Board concerning invitations to the meeting of the committee of governmental experts for the finalization of a declaration on the human genome, and the observations supplied by Mr Ernst Benda, Mr Celso Furtado, the Honourable Judge Michael Kirby, Mr Darryl Macer, Mr Benno Müller-Hill, Mr Qiu Ren-Zong and Mr Michel Revel. Comments from the World Medical Association, the Disabled People's International and Inclusion International were also included.

The information file further contained, in particular, the framework 'Convention of the Council of Europe 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'; the Opinion on the ethical aspects of patenting inventions involving elements of human origin, adopted on 25 September 1996 by the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology; the Resolution on Bioethics adopted by the Summit of the Organization of African Unity (Yaounde, July 1996).

After welcoming all participants, Mrs Noëlle Lenoir, Chairperson of the IBC, recalled that the draft text for finalization during the meeting would be the first of its kind to be of universal scope, since the only currently existing standard-setting instruments in biology and genetics were no more than national or regional in their coverage. Reminding participants of the background to the text for examination, she said that the version to be drawn up at the present meeting represented the culmination of work on many versions prior to the final stage now reached. She stressed how important it was that the instrument, after adoption by the General Conference, should enjoy lasting validity by virtue of its concern with principles. In that spirit, she added, the IBC had sought to make the future declaration prescriptive while refraining from adopting a position on scientific or biomedical practices, which were matters for national legislation.

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30. See Annex IX.

For his part, H. Ex. Mr Héctor Gros Espiell, Chairman of the Legal Commission, informed the Commission that in accordance with 28 C/Resolution 2.2, adopted by the General Conference on 15 November 1995, the Director-General had submitted to the Executive Board, when it considered item 8.3 of the agenda of its 150th Session, proposals with a view to invitations to the meeting of the committee of governmental experts entrusted with finalizing a declaration on the human genome. He emphasized the special significance of 150 EX/Decision 8.3 of the Executive Board on the convening, in July 1997, of a committee of governmental experts that would finalize the draft to be submitted, for adoption, to the General Conference at its twenty-ninth Session (October-November 1997).

The Assistant Director-General for the Directorate emphasized the importance of the task assigned to the IBC, together with its significance in connection with UNESCO's standard-setting activity. By drawing up the future declaration, UNESCO was reviving an old tradition of deciding on legal standards which had, in other fields, definitely made their mark internationally. By exploring new fields opened up by science and technology, UNESCO had, he recalled, through the IBC, updated its ethical mandate and vocation in an exemplary way. From that point of view, the IBC and its Legal Commission had brought the Organization into contact with what was most up to date and advanced at the cutting edge of scientific knowledge and research. Stating his view that adoption of the declaration would represent one of the most outstanding events of the twenty-ninth Session of UNESCO's General Conference, he reminded participants of the various stages of the process of adopting the future declaration:

- *January 1997*: communication of the preliminary draft declaration to the States and organizations invited to the meeting of the committee of governmental experts;
- *July 1997*: holding of the meeting of the committee of governmental experts to finalize a draft declaration;
- *October - November 1997*: submission for adoption of the draft declaration to the General Conference at its twenty-ninth Session.

## II. General Discussion

A member of the Commission recalled that, in the course of its preparatory work, the Commission had decided to adopt a didactic approach by dividing up the text of the future declaration into various parts. That approach had furthermore enabled the concepts that were to feature in it to be gathered together and rank-ordered. It was his view that the text of the future declaration should be in one piece, without sub-headings, for the sake of greater impact. In support of his suggestion, he cited several international declarations.

While hailed as relevant, the suggestion was nevertheless not accepted. Several IBC members observed that didactic concerns would not come to an end with the adoption of the declaration. It would be necessary, in terms of promoting the principles of the declaration, to continue to explain its content. In addition to its task of drawing up a legal instrument, the IBC must also engage in communication regarding the various bioethical issues.

Another IBC member considered that the title of the preliminary draft should put more emphasis on human rights by referring to them before the human genome. Such an inversion was regarded as affecting the ultimate purpose of the future declaration. Several participants observed that placing the human genome at the end of the title went against the whole progression of the Commission's work and, what was more, overlooked the debates of UNESCO's General Conference, which had made the human genome central to the exercise.

The subject of the future declaration being the human genome, and since a modification of the present title would be liable to limit the scope of the declaration, the Commission decided to keep the title unchanged.



### III. Article-by-Article Examination of the Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights

#### **Preamble**

An IBC member considered it necessary to reject any doctrine of the inequality of people and races. The first preambular paragraph was modified to take account of that suggestion. The second and third preambular paragraphs, for their part, were left unchanged.

#### Fourth Preambular Paragraph

Several members of the Commission expressed the wish that reference to the principle of the equal dignity of all members of the human family should echo the terms of the first preambular paragraph of the Universal Declaration of Human Rights.

#### Sixth Preambular Paragraph (new)

Various speakers took the view that the preamble had to lay emphasis both on the prospects opened up by research on the human genome and its applications and on the need for it to be conducted in a manner respectful of fundamental human rights.

#### Final Sentence of the Preamble

The members of the Commission considered that more force should be given to the proclamation of the principles set forth in the declaration. It was therefore decided to shorten the final sentence of the Preamble to make it suitably formal.

#### **Section A The Human Genome**

##### Article 1

This fundamental article, describing the human genome as common heritage of humanity, was regarded as the cornerstone of the future declaration.

##### Article 2

In subparagraph (b), the Commission deemed that the reference to 'personality' was liable to prompt a reductionist interpretation of the article. The term 'individual' was therefore preferred.

##### Article 3

Several speakers wished the article to include a reference to the impact of nutrition on the potentialities of expression of the human genome, and, in general, to that of the environment in its natural as well as its social aspects.

#### **Section B - Research on the Human Genome**

##### Article 4 (former Article 5 modified)

In view of the importance of scientific research, the Commission decided to feature at the beginning of the section the principles pertaining to and the standards deriving from it.

##### Article 5 (former Article 4)

The French of Article 5 was brought into line with the English in order that the reference to 'the respect for human dignity and human rights' should appear in both versions.

## Article 6

This article was deleted since its content was considered to overlap both with the new sixth preambular paragraph and with subparagraph (a) of the new Article 4. This deletion entailed renumbering the subsequent articles.

## ***Section C - Rights of the Persons Concerned***

### New Article 6 (former Article 7 modified)

Former Article 7 was divided into four subparagraphs, each amplifying one of the ideas that it contained. Generally speaking, the members of the Commission considered it appropriate to specify that any research on or treatment affecting the human genome must be consistent with existing national legislation. Broad support for the declaration could be secured only by taking account of national situations, which differed from country to country, particularly where health policies were concerned.

In the various articles of the section, when the term 'research', 'treatment' or 'diagnosis' was used in relation to an individual's genome, what was meant was any manipulation or alteration likely to have physical, psychological, economic, social or other repercussions. The same went for the disclosure of information on an individual's genome to the person concerned or to third parties.

The question of rigorous and prior assessment of the risks and advantages associated with research, treatment or diagnosis was discussed by the Commission at length (see also new Article 16). In the case of assessment of the risks and advantages of research, treatment or diagnosis, the question was raised of prior receipt of the free and informed consent of the person concerned or of his or her representatives. Some participants wished the instrument to provide for exceptions in special circumstances. The same went for public security requirements in democratic societies, with special reference to the prevention and punishment of crime. Courts could in some countries order a genetic test in paternity suits. In criminal cases, the genetic profiling of a defendant could likewise be ordered by a judge. The final subparagraph of the new Article 6 had been worded so as to take account of those circumstances.

Furthermore, the recourse to specific authorities, as set forth in the initial Article 7, was called into question. Speakers on the point said that, as currently worded, such a provision was liable to conflict with the national legislation of some countries where it guaranteed freedom of research. It was therefore considered preferable to state that the research protocols must be evaluated in accordance with relevant existing international standards.

### Articles 7 and 8 (former Articles 8 and 9)

Apart from their renumbering, these articles were left unchanged.

### Article 9 (former Article 10)

In the same way as for new Article 6, a reference to existing national legislation was added in order to circumscribe the right to reparation for any injuries sustained as a result of interventions affecting the human genome. While considering that the right to reparation in the event of injury was a fundamental human right, three members of the Commission, referring to the common law system, took the view that such a provision extended civil responsibility and was perhaps out of place in an international instrument. The Chairperson of the IBC spoke of the need for preventive steps, particularly with respect to research that might be conducted in developing countries, where risk control was not always guaranteed, owing to particular economic and social conditions (see also new Article 16).

## ***Section D - Conditions for the Exercise of Scientific Activity***

### Articles 10 and 11 (former Articles 11 and 12)

The expression 'research on the human genome' was preferred to 'research in biology and genetics', in order to confirm the specific field of research covered by the future declaration.

Article 12 (former Article 13)

Considering that one of the obligations of States regarding research is to foster conditions for it, the members of the Commission wished to replace the expression 'States shall provide a framework for research ...' with 'States shall determine the framework for the free exercise of research activities ...'. The words 'shall provide a framework' seemed too inhibiting; in addition to which, the reference to 'free exercise' echoed the provision on freedom of research in Article 4. In the same article, the expression 'towards bellicose ends', used initially, was deemed too restrictive. The IBC members considered that, in addition to ruling out the use of research results for the waging of wars, it was necessary to prohibit such use to prepare for wars.

Article 13 (former Article 14)

In order not to confine the role of ethics committees to mere identification of the ethical issues liable to be raised by research on the human genome, the word 'assess' was substituted for 'identify'.

**Section E - Duty of Solidarity**Article 14 (former Articles 15 and 16)

Likewise out of concern to allow in the future declaration for the possibility of widespread acceptance by States and with a realistic approach to their role, the phrase 'ensure respect for the duty of solidarity' was preferred to 'must guarantee the effectiveness of the duty of solidarity'.

Considering that the consequences of providing for solidarity have to be brought together in the same article, former Articles 15 and 16 have been recast to form only one.

Article 15 (former Article 17)

No change.

New Article 16

The Commission considered it essential to strengthen the provisions concerning international co-operation, particularly in connection with the relations between industrialized countries and developing countries already referred to in the original Article 16. Several participants stressed the importance of highlighting the role of international governmental and non-governmental organizations. The new Article 16 has therefore been divided into two paragraphs, the contents of which make it possible, respectively, to list the measures expected of States in five subparagraphs and to spell out the role of international organizations in one subparagraph.

**Section F - Promotion of the Principles Set out in the Declaration**Articles 17 and 18 (former Articles 18 and 19)

Only stylistic changes were made.

**Section G - Implementation of the Declaration**

Except for renumbering, the articles making up this section were not modified. In Article 20, however, the reference to 'human dignity and human rights' was deleted; the members of the Commission considered that all the principles set forth in the revised preliminary draft lay within the framework of the references mentioned in the Preamble, and that any superfluity would merely detract from the text.

## IV. Conclusions

After the deliberations of the eighth Session, the text of the Revised Preliminary Draft of a Universal Declaration on the Human Genome and Human Rights (20 December 1996) was approved<sup>(31)</sup>. After the stylistic corrections needed to harmonize the various language versions, the Secretariat would forward the revised preliminary draft to the Legal Commission and IBC members as early as possible.

Mrs Noëlle Lenoir thanked participants for their contribution to the revision of the preliminary draft declaration, commending the open-minded enthusiasm displayed by the members of the Legal Commission throughout the preparation of the text, and for the decisive contribution of the suggestions and observations they had made on the occasion of the collective undertaking. She informed those present that H. Ex. Mr Héctor Gros Espiell and she herself would communicate the text of the revised preliminary draft to the Director-General with a view to the meeting of the committee of governmental experts in July 1997.

She further expressed the wish that the members of the Commission and, more broadly, those of UNESCO's International Bioethics Committee should bring the revised preliminary draft to the attention of the governmental authorities of their respective countries and press for their participation in the aforesaid committee of governmental experts. She sought the co-operation of the Commission members in also helping to disseminate the revised preliminary draft among the general public and in specialist circles, in the public and private sectors alike.

The Chairperson of the IBC said that the work of the Legal Commission was merely beginning. The fact was that a veritable task of education, regarding the scope and substance of the revised preliminary draft, had to be undertaken by the time of the meeting of the committee of governmental experts and, subsequently, prior to the adoption of the declaration by the General Conference of UNESCO. Likewise, once the instrument had been adopted, the Legal Commission would have to examine the difficulties that might arise in monitoring its implementation.

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31. See Annex X.

## ***Annexes***

**METHODOLOGY FOR THE PREPARATION OF AN  
INTERNATIONAL INSTRUMENT FOR THE PROTECTION OF THE HUMAN GENOME**

(by Héctor Gros Espiell)

**I. Choice of the Legal Nature of the Possible Instrument for the Protection of the Human Genome**

***Elements for a Choice***

1. It can be a declaration or a convention. In practice, it has been observed that, since the Second World War, most of the international universal conventions concerning human rights, and prepared within the framework of the United Nations, were preceded by the adoption of a declaration or a resolution, which enabled smoother process of elaboration and implementation.
2. Nowadays, the distinction between these two forms tends to subside. Conventions, indeed, are traditionally distinguishable from declarations on account of their binding legal effect. Declarations essentially proclaim a moral commitment without a binding legal effect.
3. However, the present evolution of international public law brings us to adopt a more nuanced position. Contemporary doctrine and the International Court of Justice now seem to recognize that declarations have, under certain conditions, binding legal effect, and in particular the Universal Declaration of Human Rights.

***Chosen Form***

1. The declaration seems initially to be the most appropriate form: it enables to avoid the slowness and the constraints of the conventional procedures without being devoid of any binding legal effect.
2. The ideal would be to draw up simultaneously:
  - a short draft declaration, allowing an important place for the preamble;
  - and a draft convention, which could take up the main points of the operative sections of the declaration (included the preamble), and adding the mechanisms of its implementation.

**II. Content of the Possible Declaration**

***The Preamble***

1. It is indispensable that the declaration which could be adopted allows ample space to the preamble.
2. The necessity and the importance of a preamble, stating in general terms the objectives and the underlying principles common to the entire humanity, is justified by the two following reasons:
  - the specificity of this international instrument, which deals with a subject where the accelerated progress of research is applied almost immediately;
  - the instrument intervenes in a very sensitive area on account of its cultural, religious, political and ethical dimensions.

### ***Principles which should Figure in the Preamble***

1. The principles and the objectives on which the instrument is based should figure in the preamble.
2. In order to define the universal common principles which should appear in the preamble, it is necessary, first, to define from positive law, the principles already recognized by the various States and that concern the human genome, (freedom of research, right to life/right to live, right to health, right to privacy, etc.).

### **III. Legal Source to be Consulted**

#### ***Constitutional Law***

1. Study of the Constitutions of:
  - European countries (in particular of the European Union);
  - Eastern European countries (Poland, the Czech Republic, Hungary);
  - Latin America countries (recent Constitutions of Brazil, Colombia, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay);
  - African countries (recent Constitution of Benin).
2. Study of the jurisprudence of Supreme Courts or Constitutional Courts, notably of the United States of America, Spain, France, Italy, Germany and Austria.
3. Study of Constitutional Law

#### ***International Law***

- a. Universal Sources
  - Universal Declaration of Human Rights (1948)
  - International Covenant on Economic, Social and Cultural Rights (1966)
  - International Covenant on Civil and Political Rights (1966)
  - International United Nations Convention on the Elimination of All Forms of Racial Discrimination (1965)
  - United Nations Convention on the Elimination of All Forms of Discrimination against Women (1979)
  - United Nations Convention on the Rights of the Child (1989)
  - Resolutions of the General Assembly of the United Nations, of the Economic and Social Council and of the Commission on Human Rights (especially Resolution 1993/91 on 'Human rights and Bioethics')
  - The Vienna Declaration and Programme of Action adopted by the World Conference on Human Rights (14-25 June 1993) part I, paragraph 11, sub-para. 3
  - Resolutions of the World Health Organization (WHO) and of the World Conferences of the Food and Agriculture Organization (FAO)

#### ***UNESCO***

- The Constitution of UNESCO (1945)
- Declaration of the Principles of International Cultural Co-operation (1966)
- Recommendation on the Status of Scientific Researchers (1974)

b. Regional Sources

*Council of Europe*

- The European Convention on Human Rights of 1950 and its eight additional protocols
- Decisions of the European Commission on Human Rights and jurisprudence of the European Court of Human Rights
- Resolutions and Recommendations of the Parliamentary Assembly, of the Committee of Ministers, and of the Conferences of Ministers
- Draft Framework-Convention on Bioethics

*European Union*

- European Court of Justice
- Directives of the European Community

*Organization of American States (OAS)*

- American Declaration on the Rights and Duties of Man (1948)
- American Convention on Human Rights (1969)
- Decisions of the Inter-American Commission of Human Rights and jurisprudence of the Inter-American Court of Human Rights

*Organization of African Unity (OAU)*

- The African Charter on Human and Peoples' Rights (1981)

3. International Non-Governmental Organizations

- Conclusions and Recommendations adopted in Barcelona (1985 and 1987), as a result of the collaboration between the International Social Science Council (ISSC), the International Council for Science (ICSU), and the International Council of Philosophy and Humanistic Studies (ICPHS)
- The Declaration of Inuyama, adopted by the Twenty-fourth Conference of the Council for the International Organizations of Medical Sciences (CIOMS) (Tokyo and Inuyama, 22-27 July 1990)
- The International Ethical Guidelines for Biomedical Research Involving Human Subjects, prepared by the CIOMS in collaboration with the WHO (1993)
- The Moscow Declaration, adopted by the International Meeting on Bioethics and the Social Consequences of Biomedical Research (13-15 May 1991)
- Statement on Gene Patenting, adopted by ICSU (Paris, June 1992)
- The meeting organized by the International Centre of Studies on Bioethics (Trieste, 8-9 May 1993)
- The meeting organized by the Banco Bilbao Viscaya Foundation, in Bilbao (Spain) on 'International Co-operation for the Human Genome Project' (24-26 May 1993).



**PRELIMINARY OUTLINE OF  
A DECLARATION ON THE PROTECTION OF THE HUMAN GENOME**

(12 September 1994)

Recalling that the its third preambular paragraph of UNESCO's Constitution affirms 'the democratic principles of the dignity, equality and mutual respect of men' by rejecting 'the doctrine of the inequality of men and races'; that the fourth preambular paragraph states 'that the wide diffusion of culture, and education of humanity for justice and liberty and peace are indispensable to the dignity of man and constitute a sacred duty which all nations must fulfil in a spirit of mutual assistance and concern'; and the last preambular paragraph, by which the Organization seeks to achieve '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 proclaimed in the Universal Declaration of Human Rights of 10 December 1948 and the two International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, the UNESCO Convention against Discrimination in Education of 14 December 1960, the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the Convention on the Rights of the Child of 20 November 1989,

Bearing in mind the international instruments concerning fields more specifically related to the protection of the human genome, such as the UNESCO Universal Convention on Copyright of 6 September 1952, the WIPO Conventions on Patent and Copyright, as well as the United Nations Convention on Biological Diversity of 2 June 1992,

Recalling its resolutions 24 C/13.1, 25 C5.2 25 C/7.3 and 27 C/5.15 committing UNESCO to promote and develop ethical reflection and the action resulting therefrom with regard to scientific and technical progress in the biomedical field within the framework of the respect of human rights and freedoms,

Considering that research on the human genome and the subsequent applications open up considerable prospects for progress in the improvement of the well-being of individuals and nations and the reduction of inequalities throughout the world,

Also considering that the applications of this progress should be monitored so as to avoid the use of science for eugenic purposes arising from racial or social prejudices or from assumptions contrary to the dignity of the human person and his or her rights,

Considering besides that the human and social situations resulting from the progress in human genetics require open debate at an international level, giving all the different cultural, religious and philosophic trends of thought the possibility of voicing their opinions on problems deciding the future of humanity,

Also recalling that the principles concerning the international protection of the human genome, respecting its diversities, have as a common basis, in accordance with the Preamble of the Universal Declaration of Human Rights, '(the) recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world',

Recognizing that:

- a) everyone has the right to benefit from the progress made in human genetics in the respect of his or her dignity and freedom,
- b) research, a basic activity for the progress of knowledge, should contribute to alleviating human suffering and to the improvement of the well-being of each human being,
- c) no scientific research may prevail on the dignity, integrity and freedom of a human person,

Proclaims by this Declaration:

**the human genome common heritage of the human species.**

1. The human genome which is one of the constituent parts of the common heritage of the human species should, as such, be protected.
2. The aim of the protection of the human genome is to safeguard the integrity of the human species as a value in itself, as well as the dignity of each member of the human family.
3. Each human being has a unique genetic identity but an individual cannot be reduced to his or her genetic characteristics and has a right to the respect of his or her dignity whatever his or her genetic characteristics.
4. The genome of every human being is by nature evolutive and subject to mutations which could affect an individual and his descendants. The potential contained in the human genome is expressed differently according to the environment, education, living conditions and health of each individual.

**A. RESEARCH AND MODIFICATIONS OF THE HUMAN GENOME  
AND PROTECTION OF THE HUMAN PERSON**

5. No one can be subjected to discrimination based on their genetic characteristics.
6. No research or modification of the human genome, whether the modification has therapeutic or diagnostic aims, can be undertaken without the free and informed consent of the person concerned. In the case of minors and other legally incapacitated, parents or guardians should give such consent.
7. The confidentiality of nominative genetic data, stored or used for research or for any other end, should be protected, apart from exceptions foreseen by law.
8. Everyone has the right to obtain compensation for any damages that they have suffered due to research on, or modifications of their genome.

**B. RIGHTS AND OBLIGATIONS OF RESEARCHERS**

9. States should ensure the intellectual and the material conditions conducive to undertaking research activities on the human genome, in as much as the latter contribute to progress in the knowledge of, and the struggle against handicaps and illness.
10. The exercise of these research activities should be submitted to restrictions by States when necessary for the safeguard of human dignity or the protection of human health and environment.
11. Research in human genetics entails, taking into account its ethical and social implications, particular responsibility regarding the requirements of accuracy, prudence and intellectual honesty expected from researchers.

**C. DUTIES AND RESPONSIBILITIES TOWARDS OTHER PEOPLE**

12. States should guarantee that the community will discharge its duty of solidarity towards individuals, families and populations which, because of their characteristics, are particularly at risk of illness or handicaps.

**D. INTERNATIONAL CO-OPERATION**

13. States should undertake to appropriate steps to contribute to international dissemination of knowledge on the human genome and to scientific co-operation, especially between industrialized and developing countries.

14. States undertake to promote specific teaching on the social, ethical and medical implications of human genetics.

15. States undertake to encourage all other steps for training and information in raising the awareness of responsibility of the civil society towards the choices involved for the future by the advance in the field of human genetics.

**E. IMPLEMENTATION OF THE DECLARATION**

16. States will take the legislative measures or adopt the regulations that they deem appropriate to fulfil the objectives and goals of the present Declaration.

17. The principles and criteria outlined in the present Declaration are the standard that should be implemented by States and should be the base for any action undertaken by individuals and institutions.

18. States have the duty to promote, by teaching, education and information, respect for the above principles and criteria based on the dignity, integrity and freedom of the human person and to ensure by national and international action their universal and effective recognition and application.

19. Member States entrust the implementation of the present Declaration to the UNESCO International Bioethics Committee and, in this respect, request this Committee to formulate any recommendation that it considers appropriate to bring to their attention.

**OUTLINE OF A DECLARATION  
ON THE PROTECTION OF THE HUMAN GENOME**

(20 December 1994)

***REVISED VERSION***

Recalling that UNESCO's Constitution, in its third preambular paragraph affirms 'the democratic principles of the dignity, equality and mutual respect of men' and rejects 'the doctrine of the inequality of men and races'; that, in its fourth preambular paragraph, it stipulates 'that the wide diffusion of culture, and education of humanity for justice and liberty and peace are indispensable to the dignity of man and constitute a sacred duty which all nations must fulfil in a spirit of mutual assistance and concern'; and that, in accordance with its last preambular paragraph, 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, in the International Covenant on Economic, Social and Cultural Rights, and in the International Covenant on Civil and Political Rights of 16 December 1966, in the Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the Convention on the Rights of the Child of 20 November 1989, 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 of the Principles of International Cultural Co-operation of 4 November 1966,; the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978 and the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

Bearing in mind the international instruments relating to fields more specifically concerned with the protection of the human genome, in particular the UNESCO Universal Convention on Copyright of 6 September 1952, the WIPO Copyright and Patent Conventions, and the United Nations Convention on Biological Diversity of 5 June 1992,

Recalling 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3 and 27 C/Resolution 5.15 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 biomedical field within the framework of the respect of human rights and freedoms,

Considering that research on the human genome and the resulting applications open up vast prospects for progress in improving the well-being of individuals and nations and reducing inequalities throughout the world,

Considering also that the applications of this progress need to be regulated so as to ensure that science cannot be used for eugenic purposes, based on racial or social prejudice, or in support of principles contrary to human dignity and human rights,

Considering further that the human and social situations generated by advances in human genetics require that there should be a very open international debate enabling all shades of cultural, religious and philosophic opinion to express their views on matters of decisive importance for the future of humanity,

Recalling also that the principles relating to the international protection of the human genome are all based, in accordance with the Preamble of the Universal Declaration of Human Rights, on 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world',

Recognizing that:

- a) everyone has the right to benefit from advances in human genetics, with due regard for their dignity and freedom,
- b) research, which is an essential activity for the advance of knowledge, must contribute to the relief of human suffering and to improving the well-being of every human being,
- c) no scientific research can never take precedence over respect for human dignity and freedom,

Proclaims hereby that:

**the human genome is the common heritage of humanity.**

1. The human genome which is one of the fundamental components of the common heritage of humanity, must be protected as such.
2. The purpose of the protection of the human genome is to safeguard the integrity of humanity, as a value in itself, and the dignity of each member of the human species.
3. Each human being has a unique genetic identity which is unique, but individuals cannot be reduced to genetic characteristics and have a right to respect for their dignity regardless of those characteristics.
4. The genome of each human being is by nature evolutive and subject to changes that may affect an individual and his or her descendants. The potentialities contained in the human genome are expressed differently according to the environment, education, living conditions and state of health of each individual.

**A. RESEARCH AND OPERATIONS CONNECTED WITH THE HUMAN  
GENOME AND PROTECTION OF HUMAN BEINGS**

5. No one may be subject to discrimination on the basis of their genetic characteristics.
6. No research or operation connected with the human genome, whether conducted for the purposes of therapy or of diagnosis, can be undertaken without the free and informed consent of the person concerned. In the case of minors and incapacitated persons, such consent must be given by the legal representatives.
7. The confidentiality of genetic data associated with a names person and stored or processed for the purposes of research or any other purpose, must be protected except where the law provides otherwise.
8. Everyone has the right to be compensated for any injuries sustained as a result of an operation affecting their genome.

## **B. RIGHTS AND OBLIGATIONS OF RESEARCHERS**

9. States must ensure the intellectual and the material conditions favourable to research on the human genome, in so far as this research contributes to the advance of knowledge and to the prevention of disability and disease.
10. States may regulate research with due regard for democratic principles and whenever it is necessary for them to do so in order to safeguard human dignity protect human health or the environment.
11. In view of its ethical and social implications, research in human genetics carries special responsibilities as regards the meticulousness, caution and intellectual honesty required of researchers.

## **C. DUTIES AND RESPONSIBILITIES TOWARDS OTHER**

12. States must ensure that the community fulfils its duty of solidarity in regard to individuals, families or population groups that are particularly vulnerable to disease or disability because of their genetic characteristics.

## **D. INTERNATIONAL CO-OPERATION**

13. States shall undertake to foster the international circulation of knowledge concerning the human genome and to foster scientific co-operation, particularly between industrialized and developing countries.
14. States shall undertake to promote specific teaching concerning the ethical, social and medical implications of human genetics.
15. States shall undertake to encourage any other form of training and information that will make civil society aware of its responsibilities regarding the choices that advances in human genetics will require to be made in the future.

## **E. IMPLEMENTATION OF THE DECLARATION**

16. States shall take such legislative measures as they consider appropriate to meet the purpose of this Declaration.
17. The principles set out in this Declaration shall serve as guidance for States that adopt legislative measures for the protection of the human genome. These principles should also guide the institutions and persons responsible for the application of such measures..
18. States shall be duty bound to promote, through education and information respect for the aforementioned principles, based on human dignity and freedom, and to ensure, both nationally and internationally, that they are recognized and effectively applied.
19. The International Bioethics Committee of UNESCO shall ensure the implementation of this Declaration. For this purpose, it may make any recommendation or give any advice that it considers warranted by the circumstances.

**REVISED OUTLINE OF  
A DECLARATION ON THE PROTECTION OF THE HUMAN GENOME**

(7 March 1995)

Recalling that UNESCO's Constitution, in its third preambular paragraph, affirms 'the democratic principles of the dignity, equality and mutual respect of men' and rejects 'the doctrine of the inequality of men and races'; that, in its fourth preambular paragraph, it 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'; and that, in accordance with its last preambular paragraph, 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, in the International Covenant on Economic, Social and Cultural Rights, and in the International Covenant on Civil and Political Rights of 16 December 1966, in the Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the Convention on the Rights of the Child of 20 November 1989, 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 Declaration on Race and Racial Prejudice of 27 November 1978 and the ILO Convention (No 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

Bearing in mind the international instruments relating to fields more specifically concerned with the protection of the human genome, in particular the UNESCO Universal Copyright Convention of 6 September 1952, the WIPO Copyright and Patent Conventions, and the United Nations Convention on Biological Diversity of 5 June 1992,

Recalling 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3 and 27 C/Resolution 5.15 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 biomedical field, within the framework of respect for human rights and freedoms,

Recognizing that:

- a) research on the human genome and the resulting applications open up vast prospects for progress in improving the well-being of individuals and peoples and reducing inequalities throughout the world,
- b) the applications of genetic research must, however, be regulated in order to guard against any eugenic practice that runs counter to human dignity or human freedom,
- c) the human and social situations generated by advances in biology and human genetics require that there should be a very open international debate, ensuring the free expression of the various shades of socio-cultural, religious and philosophical opinion,

Considering lastly that the principles relating to the international protection of the human genome are all based, in accordance with the Preamble to the Universal Declaration of Human Rights, on 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world',

Proclaims hereby that:

**the human genome is the common heritage of humanity.**

1. The human genome is a fundamental component of the common heritage of humanity and needs to be protected in order to safeguard the integrity of the human species, as a value in itself, and the dignity of each of its members.
2. The human genome, which is by nature evolutive and subject to mutations, contains potentialities that are expressed differently according to the environment, education, living conditions and state of health of each family and each individual.
3. Each human being possesses a specific genetic identity. An individual's personality cannot be reduced to his or her genetic characteristics alone. All individuals have a right to respect for their dignity regardless of those characteristics.

**A. AIMS OF RESEARCH ON THE HUMAN GENOME**

4. Everyone has the right to benefit from advances in biology and human genetics, with due regard for their dignity and freedom.
5. Research, which is an essential activity of the mind, has the function, in the field of human genetics, of relieving the suffering and improving the well-being of humanity.
6. No scientific advance in this field can ever take precedence over respect for human dignity and freedom.

**B. OPERATIONS AFFECTING THE HUMAN GENOME AND HUMAN RIGHTS AND FREEDOMS**

7. No one may be subject to discrimination on the basis of their genetic characteristics.
8. No operation affecting a person's genome, whether the purpose of the operation is scientific, therapeutic or diagnostic, may be undertaken without the prior, free and informed consent of the person concerned or, where appropriate, of his or her duly authorized representatives.
9. The confidentiality of genetic data associated with a named person and stored or processed for the purposes of research or any other purpose, must be protected from third parties except where the law provides otherwise and where justified by the general interest.
10. Everyone has the right to be compensated for any injuries sustained as a result of an operation directly affecting their genome.

**C. RIGHTS AND OBLIGATIONS OF RESEARCHERS**

11. States shall ensure the intellectual and the material conditions favourable to research on the human genome, in so far as this research contributes to the advance of knowledge and to the prevention of disability and disease.



12. States shall regulate research with due regard for democratic principles and whenever it is necessary for them to do so in order to safeguard human dignity and freedom and protect health or the environment.

13. In view of its ethical and social implications, research in human genetics entails special responsibilities as regards the meticulousness, caution and intellectual honesty required of researchers.

#### **D. DUTIES AND RESPONSIBILITIES TOWARDS OTHERS**

14. States must ensure that the community fulfils its duty of solidarity in regard to individuals, families or population groups that are particularly vulnerable to disease or disability because of their genetic characteristics.

#### **E. INTERNATIONAL CO-OPERATION**

15. States shall undertake to foster the international spread of scientific culture concerning the human genome and to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

16. States shall undertake to promote specific teaching concerning the ethical, social and medical implications of biology and human genetics.

17. States shall undertake to encourage any other form of research, training and information calculated to make civil society aware of its responsibilities regarding the choices made necessary by advances in biology and human genetics.

#### **F. IMPLEMENTATION OF THE DECLARATION**

18. States shall adopt such normative measures as they consider appropriate to meet the purpose of this Declaration.

19. The principles set out in this Declaration shall serve as a basis for the normative measures adopted by States. They shall also guide those in charge of institutions, and any other persons responsible for the application of such measures.

20. States shall be duty bound to promote, through education, training and information, respect for the aforementioned principles, based on human dignity and freedom, and to ensure, both nationally and internationally, that they are recognized and effectively applied.

21. The International Bioethics Committee of UNESCO shall ensure the implementation of this Declaration. For this purpose, it may make recommendations or give advice.

**PRELIMINARY DRAFT OF  
AN INTERNATIONAL DECLARATION ON THE HUMAN GENOME  
IN RELATION TO THE PROTECTION OF HUMAN RIGHTS**

(5 January 1996)

***PROVISIONAL VERSION***

**Explanatory Note**

Compared to the outline of a declaration dated 7 March 1995, the provisional version presented herewith includes several modifications. The modifications concerned have been proposed by:

- the fifth meeting of the Legal Commission, 25 September 1995;
- the third session of the IBC, 29 September 1995;
- Commission III, 'The sciences in the service of development', of the twenty-eighth session of the General Conference during the debate on the future declaration, 9 and 19 November 1995;
- international inter-governmental or non-governmental organizations, academic institutions and universities (Academies of Sciences, Law faculties, etc.) or personalities consulted jointly by Mrs Noëlle Lenoir, Chairperson of the IBC, and H. Ex. Mr Héctor Gros Espiell, Chairman of the Legal Commission of the IBC, between June and December 1995.

Two changes suggested during the third session of the IBC do not appear in this preliminary draft.

Firstly, a new formulation of paragraph 7 has been suggested as follows: 'Discrimination on grounds of genetic characteristics shall be allowed only for good cause to protect the individual or others'. What is intended by such a formulation is obvious. It brings to mind the often-quoted case of a commercial pilot likely to suffer a heart attack and who could put the lives of several hundred people in jeopardy. Even so, the new formulation of this paragraph is not adequate, as it makes a general formulation on the basis of particular cases.

Secondly, a new preambular paragraph, which would be placed between the third and fourth preambular paragraphs, has been suggested as follows: 'Knowing that genetic diversity, when it exists, is a factor of progress of humanity and that it reflects the influence of the environment on the human genome, and that we should not draw any social or political conclusions,'.

The text concerned suggest at least three statements which are not on the same level of analysis. The aim is to use only scientific arguments supporting genetic diversity to neither encourage nor discourage it. If the Legal Commission decides to deal with this issue in the future version of the declaration, it should choose between a new preambular paragraph or new phrasing to give a simple and explicit formulation.

**PRELIMINARY DRAFT OF AN INTERNATIONAL DECLARATION  
ON THE PROTECTION OF HUMAN GENOME IN RELATION  
TO THE PROTECTION OF HUMAN RIGHTS**

(5 January 1996)

**PROVISIONAL VERSION<sup>(32)</sup>**

Recalling that UNESCO's Constitution, in its third preambular paragraph, affirms 'the democratic principles of the dignity, equality and mutual respect of men' and rejects 'the doctrine of the inequality of men and races'; that, in its fourth preambular paragraph, it 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', ***that, in its fifth preambular paragraph, it proclaims that 'peace must therefore be founded (...) upon the intellectual and moral solidarity of mankind'***, and that, in accordance with its last preambular paragraph, 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, in the International Covenant on Economic, Social and Cultural Rights, and in the International Covenant on Civil and Political Rights of 16 December 1966, in the Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the Convention on the Rights of the Child of 20 November 1989, 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 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 and the ILO Convention (No 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

Bearing in mind the international instruments ~~relating to fields more specifically concerned with the protection of the human genome,~~ ***likely to have a bearing on the applications of genetics***, in particular the UNESCO Universal Copyright Convention of 6 September 1952, the WIPO Copyright and Patent Conventions, and the United Nations Convention on Biological Diversity of 5 June 1992,

Recalling ***22 C/Resolution 13.1, 23 C/Resolution 13.1, 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3 and 27 C/Resolution 5.15, 28 C/Resolution 0.12, 28 C/Resolution 2.1 and 28 C/Resolution 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 ~~biomedical~~ ***field of biology and genetics***, within the framework of respect for human rights and freedoms,

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32. In this provision version, the words deleted are ~~crossed-out~~; words added are in ***bold italic*** print.

Recognizing that:

- a) research on the human genome and the resulting applications open up vast prospects for progress in improving the well-being of individuals and *all* peoples, ~~and reducing inequalities throughout of~~ the world,
- b) the applications of genetic research must, however, be regulated in order to guard against any eugenic practice that runs counter to human dignity or ~~to~~ human ~~freedom~~ *rights*,
- c) the human and social situations generated by advances in human biology and genetics require that there should be a very open international debate, ensuring the free expression of the various shades of socio-cultural, religious and philosophical opinion,

Considering lastly that the principles relating to ~~the international protection of~~ the human genome *and to the protection of the human person* based, in accordance with the Preamble to the Universal Declaration of Human Rights, on 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world',

Proclaims hereby that:

**the human genome is the common heritage of humanity.**

1. The human genome is a fundamental component of the common heritage of humanity and needs to be protected in order to safeguard the integrity of the human species, as a value in itself, and the dignity *and the rights* of each of its members.
2. 3. The human genome, which is by nature evolutive and subject to mutations, contains potentialities that are expressed differently according to the environment, education, living conditions and state of health of each family and each individual.
3. 2. *The genome of each human being possesses a individual represents his or her* specific genetic identity *without reducing an the* individual's personality ~~cannot be~~ reduced to his or her genetic characteristics alone. All individuals have a right to respect for their dignity regardless of those characteristics.

<b>A. AIMS OF RESEARCH ON THE HUMAN GENOME</b>
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4. Everyone has the right to benefit from advances in biology and human genetics, with due regard for their dignity and ~~freedom~~ *rights*.
5. Research, which is an essential activity of the mind, has the function, in the field of human *biology and* genetics, *of advancing knowledge*, of relieving the suffering and improving the well-being of humanity.
6. No scientific advance in this field ~~can may ever take precedence over~~ *be contrary to* respect for human dignity and ~~freedom~~ *human rights*.

<b>B. OPERATIONS AFFECTING THE HUMAN GENOME AND HUMAN RIGHTS AND FREEDOMS</b>
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7. No ~~one~~ *person* may be subject to discrimination on the basis of their genetic characteristics.

8. ~~No~~ **An** operation affecting a person's genome, ~~whether the purpose of the operation is~~ **may have no purpose other than** scientific, therapeutic or diagnostic. **Such an operation may not** be undertaken without **a risk/benefit assessment nor without** the prior, free and informed consent of the person concerned or, where appropriate, of his or her duly authorized representatives, **who will be mindful of the superior interest of the person concerned.**

9. The confidentiality of genetic data associated with a named person and stored or processed for the purposes of research or any other purpose, must be protected from third parties. ~~except where the law provides otherwise~~ **No exception may be made to this principle but under the conditions foreseen by law** and where justified by the general interest.

10. Everyone has ~~the a~~ right ~~to be compensated~~ **equitable compensation** for any injuries sustained as a **the direct** result of an operation ~~directly~~ affecting their genome.

#### C. RIGHTS AND OBLIGATIONS OF RESEARCHERS

11. States shall ensure the intellectual and the material conditions favourable to research on the human genome, in so far as this research contributes to the advance of knowledge, ~~and to the prevention of disability and disease~~ **to the relief of suffering and to the improvement of the well-being of humanity.**

12. States shall regulate research with due regard for democratic principles ~~and whenever it is necessary for them to do so~~ in order to **safeguard guarantee the protection of** human dignity and **freedom human rights,** ~~and protect the protection of~~ health ~~or the as well as that of the~~ environment.

13. In view of its ethical and social implications, research in human genetics entails special responsibilities as regards the meticulousness, caution and intellectual honesty required of researchers.

#### D. DUTIES AND RESPONSIBILITIES TOWARDS OTHERS

14. States must ensure that the community fulfils its duty of solidarity in regard to individuals, families or population groups that are particularly vulnerable to disease or disability ~~because of their genetic characteristics~~ **in connection with genetic anomalies.**

**14bis. States recognize the importance of promoting the creation of multidisciplinary, pluralistic and independent ethics committees, with the task of identifying the ethical, social and human issues raised by research and operations on the human genome.**

#### E. INTERNATIONAL CO-OPERATION

15. States shall undertake to foster the international dissemination of scientific ~~culture~~ **knowledge** concerning the human genome and to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

16. States shall undertake to promote specific teaching **and research** concerning the ethical, social and medical **grounds and** implications of human biology and genetics.

17. States shall undertake to encourage any other form of research, training and information calculated to ~~make civil society aware~~ **strengthen society's awareness** of its responsibilities regarding the **fundamental** choices made necessary by advances in human biology and genetics.

F. IMPLEMENTATION OF THE DECLARATION
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18. States shall **undertake to** adopt such normative measures as they consider appropriate to meet the purpose of this Declaration.

19. The principles set out in this Declaration shall serve as a basis for the normative measures adopted by States. They shall also guide those in charge of institutions, and any other persons responsible for the ~~application~~ **implementation** of such measures.

20. States shall ~~be duty-bound~~ **undertake** to promote, through education, training and information, respect for the aforementioned principles, based on human dignity and ~~freedom~~ **human rights**, and to ensure, both nationally and internationally, that they are recognized and effectively applied.

21. The International Bioethics Committee of UNESCO shall ensure ~~the implementation of the~~ **respect of the principles set forth in** this Declaration. For this purpose, it may make recommendations ~~or~~ **and** give advice.

**21bis. Nothing in this Declaration may be used by any State, group or person to ends contrary to the principles set forth herein.**

**PRELIMINARY DRAFT OF A UNIVERSAL DECLARATION  
ON THE HUMAN GENOME AND HUMAN RIGHTS**

(29 January 1996)

**PROVISIONAL VERSION 2 <sup>(33)</sup>**

*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 'the 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 Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, in the Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the Convention on the Rights of the Child of 20 November 1989, 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 and the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

*Bearing in mind* the international instruments which could have a bearing on the applications of genetics, *inter alia*, in the field of copyright, the UNESCO Universal Convention and the WIPO Convention, revised on 24 July 1971, in the field of intellectual property, the Paris Convention of 20 March 1883, as last revised at Stockholm on 14 July 1967, and the Budapest Treaty on International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures of 28 April 1977,

*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 biological diversity, as a constituent element of humanity, should not give rise to any interpretation of a social or political nature which could call into question the fundamental principle of equal dignity inherent in all members of the human family,

*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 freedoms,

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33. This provisional version take into account modifications proposed by the Legal Commission of the IBC at its sixth meeting, on 25 January 1996.

*Recognizing that:*

- a) research on the human genome and the resulting applications open up vast prospects for progress in improving the health and well-being of individuals and of humankind as a whole,
- b) the applications of genetic research must, however, be regulated in order to guard against any eugenic practice that runs counter to human dignity and human rights,
- c) the human and social situations generated by advances in biology and genetics require that there should be a very open international debate, ensuring the free expression of the various shades of socio-cultural, religious and philosophical opinion,

*Considering* that the principles relating to the human genome and the protection of the individual based, in accordance with the preamble to the Universal Declaration of Human Rights, on 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world',

*Proclaims* that the human genome is the common heritage of humanity and hereby *adopts* the principles set forth in the present Declaration.

## A. THE HUMAN GENOME

### *Article 1*

The human genome is a fundamental component of the common heritage of humanity.

### *Article 2*

- a) The genome of each individual represents his or her specific genetic identity.
- b) An individual's personality cannot be reduced to his or her genetic characteristics alone.
- c) Everyone has a right to the respect of their dignity and of their rights regardless of these characteristics.

### *Article 3*

The human genome, which is by nature evolutive and subject to mutations, contains potentialities that are expressed differently according to the environment, education, living conditions and state of health of each family and each individual.

## B. RESEARCH ON THE HUMAN GENOME

### *Article 4*

The protection of the individual with respect to the implications of research in biology and genetics is designed to safeguard the integrity of the human species, as a value in its own right, as well as the respect for the dignity, freedom and the rights of each of its members.

### *Article 5*

- a) Research, which is an essential activity of the mind, has the function, in the fields of biology and genetics, of advancing knowledge, relieving suffering and improving the health and well-being of the individual and of humankind as a whole.
- b) Everyone has the right to benefit from advances in biology and genetics, with due regard to his or her dignity and rights.

### *Article 6*

No scientific advances in this field may ever be contrary to the respect for human dignity and human rights.



**C. INTERVENTIONS AFFECTING THE HUMAN GENOME***Article 7*

No intervention affecting a person's genome may be undertaken without rigorous and prior assessment of the risks and benefits pertaining thereto and without prior, free and informed consent of the person concerned or, where appropriate, of his or her duly authorized representatives, guided by the person's best interests.

*Article 8*

No one may be subjected to discrimination on the basis of genetic characteristics that aims to or has the effect of injuring human dignity, freedom or rights on the grounds of equality.

*Article 9*

The confidentiality of genetic data associated with a named person and stored or processed for the purposes of research or any other purpose, must be protected from third parties.

*Article 10*

Every individual has the right to just reparation for any injuries sustained as a direct result of an intervention affecting his or her genome.

**D. RIGHTS AND OBLIGATIONS OF RESEARCHERS***Article 11*

States shall ensure the intellectual and the material conditions favourable to research on the human genome, in so far as this research contributes to the advance of knowledge, the relief of suffering and the improvement of the health and well-being of the individual and of humankind as a whole.

*Article 12*

States shall provide a framework for research with due regard for democratic principles, in order to safeguard the dignity and rights of the individual, the protection of health as well as that of the environment.

*Article 13*

In view of its ethical and social implications, research in biology and genetics entails special responsibilities as regards the meticulousness, caution and intellectual honesty required of researchers.

**E. DUTIES AND RESPONSIBILITIES TOWARDS OTHERS***Article 14*

States must ensure that the community fulfils its duty of solidarity towards individuals, families and population groups that are particularly vulnerable to disease or disability linked to anomalies of a genetic character.

*Article 15*

States shall recognize the value of promoting, at various appropriate levels, the establishment of independent, multidisciplinary and pluralist ethics committees to identify ethical, social and human issues raised by research and interventions affecting the human genome.

**F. INTERNATIONAL CO-OPERATION***Article 16*

States shall undertake to foster the international dissemination of scientific knowledge concerning the human genome and to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

*Article 17*

States shall undertake to promote specific teaching and research concerning the ethical, social and human foundations and implications of biology and genetics.

*Article 18*

States shall undertake to encourage any other form of research, training and information conducive to raising the awareness of society of its responsibilities regarding the basic choices entailed by advances in biology and genetics.

**G. IMPLEMENTATION OF THE DECLARATION***Article 19*

States shall undertake to adopt such measures as they consider appropriate to ensure that the principles set out in this Declaration are respected.

*Article 20*

The principles set out in this Declaration, which shall serve as a basis for the normative measures adopted by States, shall also guide all authorities and other persons responsible for their implementation.

*Article 21*

States shall undertake to promote, through education, training and information, respect for the aforementioned principles, based on human dignity and human rights and to foster their recognition and effective application, and to ensure, both nationally and internationally, that they are recognized and effectively applied.

*Article 22*

The International Bioethics Committee of UNESCO shall monitor observance of the principles set out in this Declaration. For this purpose, it may make recommendations and give advice.

*Article 23*

No provision of this Declaration may be used by any State, group or person to ends contrary to the principles set forth herein.

**INTERNATIONAL CONSULTATION ON THE OUTLINE  
OF A UNESCO DECLARATION ON THE HUMAN GENOME**

**PERSONALITIES AND ORGANIZATIONS  
HAVING PROVIDED COMMENTS ON  
THE FUTURE DECLARATION OF UNESCO**

**I. Members of the Legal Commission of the IBC**

Mr Mohammed Bedjaoui (Algeria)  
President of the International Court of Justice

Mr Mohammed Bennouna (Morocco)  
Director of the Arab World Institute

Mr Harold Edgar (United States of America)  
Director of the Julius Silver Program in Law, Science and Technology,  
Columbia University School of Law

Mr Gonzalo Figueroa Yañez (Chile)  
Director of the *Escuela de Graduados* of the Faculty of Law, University of Chile

Mr Guido Gerin (Italy)  
President of the International Institute for the Study of Human Rights

Mr Héctor Gros Espiell, President of the Legal Commission of the IBC (Uruguay)  
Ambassador, Permanent Delegate of Uruguay to UNESCO

Mrs Bartha Maria Knoppers (Canada)  
Research Centre of Private Law of the Faculty of Law, University of Montreal

Mrs Noëlle Lenoir, President of the IBC (France)  
Member of the *Conseil Constitutionnel* of France

Mr Kéba M'Baye (Senegal)  
Former Vice-President of the International Court of Justice

Mrs Marie-Madeleine Mborantsuo (Gabon)  
President of the Constitutional Court of Gabon

Mr Otakar Motejl (Czech Republic)  
President of the Supreme Court of the Czech Republic

Mr Yasuhito Saito † (Japan)  
Professor of International Law, Asia University

**II. Members of the IBC**

Mr Sidney Altman (United States of America)  
Nobel Prize of Chemistry (1989)  
Sterling Professor of Biology, Yale University

Mr Julio A. Barberis (Argentina)  
Professor of International Law, Catholic University of Buenos Aires

Mrs Chee Heng Leng (Malaysia)  
Dept. of Nutrition & Community Health, Faculty of Human Ecology,  
*Universiti Pertanian Malaysia*

Mr Ricardo Cruz-Coke (Chile)  
Director of the Genetic Unit, Hospital J.J. Aguirre, University of Chile

Mr Norio Fujiki (Japan)  
Doctor of Medicine, Fukui Medical School

Mr Ryuichi Ida (Japan)  
Professor of International Law, Kyoto University

Mr Peter Lachmann (United Kingdom)  
Vice-President of The Royal Society

Mr Darryl Macer (New Zealand)  
Foreign Professor, University of Tsukuba (Japan)

Mr Hans-Martin Sass (Germany)  
Professor of Philosophy, *Ruhr Universität*

### **III. International Inter-governmental and Non-governmental Organizations**

Academia Europaea (United Kingdom)

*Association internationale Droit, Ethique et Science* (France)

Bioethics Commission of the International Federation of Philosophical Societies (FISP) (Belgium)  
(2 contributions)

Council for International Organizations of Medical Sciences (CIOMS)

European Academy of Arts, Sciences and Humanities (France)

The Human Genome Organization (HUGO) (United States of America)

Inclusion International (Switzerland)

International Bar Association (IBA) (United Kingdom)

International Council for Science (ICSU) (France)  
(4 contributions)

International Federation of Catholic Pharmacists (Belgium)

International Humanist and Ethical Union (IHEU) (The Netherlands)

International Labour Office (ILO)

International Network of Engineers and Scientists for Global Responsibility (INES)  
(2 contributions)

International Society for Artificial Organs (United Kingdom)

United Nations Organization (UN)

United Nations Environment Programme (UNEP)

United Nations Fund for Population Activities (UNFPA)

World Federation of Scientific Workers (WFSW) (United Kingdom)

World Health Organisation (WHO)

World Intellectual Property Organization (WIPO)

#### **IV. National Institutions**

Academy of Medical Sciences, Committee of Bioethics (Romania)

Ad hoc Committee to study the revised outline of a declaration on the human genome of 7 March 1995 (Australia)

*Association française de psychiatrie* (France)

Center for Applied Ethics, The University of British Columbia (Canada)

Center for Ethics in the Sciences and Humanities (Germany)

Chinese Academy of Sciences (China)

Commission of the French Republic for Education, Science and Culture (France)

*Commission nationale consultative des droits de l'homme (Groupe de travail D)* (France)

*Commission nationale de l'informatique et des libertés* (CNIL) (France)

The Israel Society for Medical Ethics (Israel)

*Koninklijke Academie voor Wetenschappen* (Belgium)

*Medizinische Sektion am Goetheanum, Arbeitsgruppe Medizinesche Ethik* (Switzerland)

*Mouvement contre le racisme et pour l'amitié entre les peuples* (MRAP) (France)

National Commission of Malaysia for UNESCO (Malaysia)

Oswaldo Cruz Foundation (Brazil)

*Projektgruppe A-GENS* (Germany)

Royal Belgian Academy of Medicine (Belgium)

*Schweizerische Akademie der Medizinischen Wissenschaften* (Switzerland)

*Société camerounaise de bioéthique* (Cameroon)

*Universidad Nacional del Sur, Centro de Investigaciones Bioéticas* (Argentina)

#### **V. Personalities**

Mrs Irma Arnoux (France),  
University of Bordeaux

Mr Salvador D. Bergel (Argentina),  
UNESCO Chair in Bioethics, University of Buenos Aires

Mr Carsten Braun (Germany),  
Martin Luther University

Dr M. Braun (Germany),  
Psychotherapist

Mrs Hiltrud Breyer (Germany),  
Member of the European Parliament

Mrs Janine Chanteur (France),  
Professor of Philosophy, University of Paris-Sorbonne

Mr Gérard Cohen-Jonathan (France),  
University of Paris II, Honorary Dean of the Faculty of Law, Strasbourg

Mr James Crawford and Mr John Keown (United Kingdom),  
Research Centre for International Law, University of Cambridge

Mrs Marie-Claude Dock (Switzerland),  
Vice-President of the *Association française des juristes démocrates*

Mrs Thomais Douraki (Greece),  
Legal Counsel of the Ministry of National Economy

Mr J.C. Galloux (France),  
University of Versailles

Mr Ram Ishay (Israel),  
The Israel Society for Medical Ethics

Dr S.P. Jagota (India),  
Former President of the United Nations International Law Commission

Mr Maurice Kamto (Cameroon),  
Professor of Law

Lord Wayland Kennet (United Kingdom),  
House of Lords

Mr Alexandre Kiss (France),  
Professor of International Law

Mr Alain Lejeune (Belgium),  
Belgian Bioethics Association

Mr Wolf Lepenies (Germany)  
Institute for Advanced Study

Mrs Ilse Maresch (Germany),  
*Arbeitsstelle in der Evangelischen Kirche im Rheinland für sozioethische Fragen der Bio- und  
Medizintechnologien*

Mr Alex Mauron (Switzerland),  
Louis-Jeantet Foundation of Medicine

Mr Dietmar Mieth and Mr Marcus Düwell (Germany),  
University of Tübingen

Mr Alain Pellet (France),  
University of Paris-Nord,  
Member of the United Nations International Law Commission

Mr Louis Pettiti (France),  
Judge at the European Court of Human Rights

Mr Michel Prieur (France),  
Dean of the Faculty of Law, University of Limoges

Mr Carlos M. Romeo-Casabona (Spain)  
Chair of Law and Human Genome, University of Deusto

Mr Shabtai Rosenne (Israel),  
Professor of International Law

Mrs Jacqueline Rubellin-Devichi (France),  
Director of the *Centre de droit de la famille*, Jean-Moulin University, Lyon 3

Mrs Jacqueline Russ (France),  
Professor of Philosophy

Mr George P. Smith, II (United States of America),  
The Catholic University of America

Mr Nicholas Tonti-Filippini (Australia),  
Independent Consultant Ethicist

**PRELIMINARY DRAFT OF  
A UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS**

(4 March 1996)

*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 'the 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 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 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 and the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

*Bearing in mind* the international instruments which could have a bearing on the applications of genetics in the field of industrial 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, and 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,

*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 biological diversity of humanity should not give rise to any interpretation of a social or political nature which could call into question the fundamental principle of equal dignity inherent in all members of the human family,

*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 freedoms,

*Recognizing* that:

- a) research on the human genome and the resulting applications open up vast prospects for progress in improving the health and well-being of individuals and of humankind as a whole,
- b) the applications of genetic research must, however, be regulated in order to guard against any eugenic practice that runs counter to human dignity and human rights,
- c) the results of research on the human genome should in no case be used towards military or bellicose ends,
- d) the human and social situations generated by advances in biology and genetics require that there should be a very open international debate, ensuring the free expression of the various shades of socio-cultural, religious and philosophical opinion,

*Considering* that the principles relating to the human genome and the protection of the individual based, in accordance with the preamble to the Universal Declaration of Human Rights, on 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world',

*Proclaims* that the human genome is the common heritage of humanity and hereby *adopts* the principles set forth in the present Declaration.

## A. THE HUMAN GENOME

### *Article 1*

The human genome is a fundamental component of the common heritage of humanity.

### *Article 2*

- a) The genome of each individual represents his or her specific genetic identity.
- b) An individual's personality cannot be reduced to his or her genetic characteristics alone.
- c) Everyone has a right to the respect of their dignity and of their rights regardless of these characteristics.

### *Article 3*

The human genome, which is by nature evolutive and subject to mutations, contains potentialities that are expressed differently according to the environment, education, living conditions and state of health of each family and each individual.

## B. RESEARCH ON THE HUMAN GENOME

### *Article 4*

The protection of the individual with respect to the implications of research in biology and genetics is designed to safeguard the integrity of the human species, as a value in its own right, as well as the respect for the dignity, freedom and the rights of each of its members.



*Article 5*

- a) Research, which is an essential activity of the mind, has the function, in the fields of biology and genetics, of advancing knowledge, relieving suffering and improving the health and well-being of the individual and of humankind as a whole.
- b) Everyone has the right to benefit from advances in biology and genetics, with due regard to his or her dignity and rights.

*Article 6*

No scientific advances in the fields of biology and genetics should ever prevail over the respect for human dignity and human rights.

<b>C. INTERVENTIONS AFFECTING THE HUMAN GENOME</b>
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*Article 7*

No intervention affecting an individual's genome may be undertaken, whether for scientific, therapeutic or diagnostic purposes, without rigorous and prior assessment of the risks and benefits pertaining thereto and without prior, free and informed consent of the person concerned or, where appropriate, of his or her duly authorized representatives, guided by the person's best interests.

*Article 8*

No one may be subjected to discrimination on the basis of genetic characteristics and that aims or has the effect of injuring the recognition of human dignity or the enjoyment of his or her rights on the grounds of equality.

*Article 9*

The confidentiality of genetic data associated with a named person and stored or processed for the purposes of research or any other purpose, must be protected from third parties.

*Article 10*

Every individual has the right to just reparation for any injuries sustained as a direct result of an intervention affecting his or her genome.

<b>D. RIGHTS AND OBLIGATIONS OF RESEARCHERS</b>
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*Article 11*

States shall ensure the intellectual and the material conditions favourable to research on the human genome, in so far as this research contributes to the advance of knowledge, the relief of suffering and the improvement of the health and well-being of the individual and of humankind as a whole.

*Article 12*

States shall provide a framework for research with due regard for democratic principles, in order to safeguard the dignity and rights of the individual, to protect public health and the environment.

*Article 13*

In view of its ethical and social implications, research in biology and genetics entails special responsibilities as regards the meticulousness, caution and intellectual honesty required of researchers.

## **E. DUTIES AND RESPONSIBILITIES TOWARDS OTHERS**

### *Article 14*

States must guarantee the effectiveness of the duty of solidarity towards individuals, families and population groups that are particularly vulnerable to disease or disability linked to anomalies of a genetic character.

### *Article 15*

States shall recognize the value of promoting, at various appropriate levels, the establishment of independent, multidisciplinary and pluralist ethics committees to identify ethical, social and human issues raised by research and interventions affecting the human genome.

## **F. INTERNATIONAL CO-OPERATION**

### *Article 16*

States shall undertake, with due regard for democratic principles, to foster the international dissemination of scientific knowledge concerning the human genome and to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

### *Article 17*

States shall undertake to promote specific teaching and research concerning the ethical, social and human foundations and implications of biology and genetics.

### *Article 18*

States shall undertake to encourage any other form of research, training and information conducive to raising the awareness of society of its responsibilities regarding the basic choices entailed by advances in biology and genetics.

## **G. IMPLEMENTATION OF THE DECLARATION**

### *Article 19*

States shall undertake to ensure that the principles set out in this Declaration are respected.

### *Article 20*

The principles set out in this Declaration shall guide all authorities and other persons responsible for their implementation.

### *Article 21*

States shall undertake to promote, through education, training and information, respect for the aforementioned principles, based on human dignity and human rights and to foster their recognition and effective application.

### *Article 22*

The International Bioethics Committee of UNESCO shall monitor observance of the principles set out in this Declaration. For this purpose, it may make recommendations and give advice.

### *Article 23*

No provision of this Declaration may be used by any State, group or person to ends contrary to the principles set forth herein.

**REVISED PRELIMINARY DRAFT OF A  
UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS<sup>(34)</sup>**

(10 December 1996)

*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 'the 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 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 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 and the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

*Bearing in mind* the international instruments which could have a bearing on the applications of genetics in the field of ~~industrial 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 1<sup>st</sup> January 1995**],

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34. In order to facilitate the comparison between the present text and the Preliminary Draft dated 4 March 1996, proposed elimination of words or sentences are indicated in characters ~~crossed-out~~. Those which have been added are shown in **[bold and in square brackets]**. The text also includes editorial improvements, underlines, which have been suggested by members of the IBC.

*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 biological diversity of humanity should not give rise to any interpretation of a social or political nature which could call into question the fundamental principle of equal dignity inherent in all members of the human family;*

*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 freedoms,*

*Recognizing that:*

- a) ~~Research on the human genome and the resulting applications open up vast prospects for progress in improving the health and well-being of individuals and of humankind as a whole, (see Article 5)~~
- b) ~~Applications of genetic research must, however, be regulated in order to guard against any eugenic practice that runs counter to human dignity and human rights, (see Article 13)~~
- c) ~~Results of research on the human genome should in no case be used towards military, or bellicose ends, (see Article 13)~~
- d) ~~Human and social situations generated by advances in biology and genetics require that there should be a very open international debate, ensuring the free expression of the various shades of socio-cultural, religious and philosophical opinion, (see Article 19)~~

~~Considering that the principles relating to the human genome and the protection of the individual based, in accordance with the Preamble to the Universal Declaration of Human Rights, on 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family (which) is the foundation of freedom, justice and peace in the world'; (see below)~~

~~Proclaims that the human genome is the common heritage of humanity and hereby adopts the principles set forth in the present Declaration [which have as their common basis 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family', in accordance with the Preamble to the Universal Declaration of Human Rights].~~

## A. THE HUMAN GENOME

### *Article 1*

The human genome, [**inasmuch as it underlines the fundamental unity of all members of the human family and the dignity with which each is endorsed,**] is a fundamental component of the common heritage of humanity.

### *Article 2*

- a) The genome of each individual represents his or her specific genetic identity.
- b) An individual's personality ~~can~~ is not be reduced to his or her genetic characteristics ~~alone~~.
- c) Everyone has a right to ~~the~~ respect ~~of~~ for their dignity and ~~of~~ for their rights regardless of ~~these~~ their genetic characteristics.

### *Article 3*

The human genome, which ~~is~~ by its nature ~~evolutive~~ evolves and ~~is~~ subject to mutations, contains potentialities that are expressed differently according to education the environment, living conditions and state of health of each family and each individual.

<b>B. RESEARCH ON THE HUMAN GENOME</b>
--

*Article 6 [Article 4]*

No scientific ~~advances research or its applications~~ in the fields of biology and genetics should ~~ever be allowed to~~ prevail over the respect for human dignity and human rights.

*Article 5*

- a) Research, ~~which is an essential activity of the mind, has the function,~~ [an expression of the freedom of thought, contributes to the progress of] advancing knowledge, [especially] in ~~the fields of~~ biology and genetics, ~~of~~ [to] relieving suffering and [to] improving the health and well-being of ~~the~~ individuals and of humankind as a whole.
- b) Everyone ~~has the right~~ [must be able] to benefit from advances in biology and genetics, with due regard to ~~his or her~~ their dignity and rights.

*Article 4 [Article 6]*

The protection of the individual with respect to the implications of research in biology and genetics is designed to safeguard the integrity of ~~the human species~~ humanity, as a value in its own right, as well as ~~the~~ to ensure respect for the dignity, freedom and the rights of each of its members.

<b>C. INTERVENTIONS AFFECTING THE HUMAN GENOME [RIGHTS OF THE PERSONS CONCERNED]</b>
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*Article 7*

No ~~intervention affecting an individual's genome may be undertaken, whether for scientific, therapeutic or diagnostic purposes~~ [research, treatment or diagnosis affecting an individual's genome may be undertaken] without rigorous and prior assessment of the risks and benefits pertaining thereto and without ~~the~~ prior, free and informed consent of the person concerned or, ~~where appropriate~~ [if he or she is not in a position to give it,] of his or her duly authorized representatives, guided by the person's best interests. [In the case of research, this assessment must be submitted to an authority, meeting the criteria set out in Article 14 below, which shall pronounce on both the scientific and the ethical aspects.]

*Article 8*

No one may be subject to discrimination ~~on the basis of~~ based on genetic characteristics ~~and that aims is intended to diminish~~ or has the effect of ~~injuring the recognition of~~ diminishing human dignity or ~~impairing the enjoyment of his or her rights to be treated equally on the grounds of equality.~~

*Article 9*

~~The confidentiality of~~ Genetic data associated with a named person and stored or processed for the purposes of research or any other purpose must be held confidential and protected against disclosure from to third parties.

*Article 10*

Every individual has the right to a just reparation for any injuries sustained as a direct result of an intervention affecting his or her genome.

**D. RIGHTS AND OBLIGATIONS OF RESEARCHERS**  
**[ CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY ]**

*Article 13 [Article 11]*

In view of its ethical and social implications, research in biology and genetics entails special responsibilities as regards the meticulousness, caution and intellectual honesty **[and integrity]** required of researchers, **[both in conducting their research and in presenting and exploiting their findings]**.

*Article 14 [Article 12]*

States shall ~~ensure~~ **[foster]** the intellectual and the material conditions favourable to **[freedom in the conduct of]** research ~~on the human genome [in biology and genetics], in so far as this research contributes to the advance of knowledge, the relief of suffering and the improvement of the health and well-being of the individual and of humankind as a whole [on the basis of the principles and subject to the reservations set out in this Declaration]~~.

*Article 12 [Article 13]*

States shall provide a framework for research with due regard for democratic principles, in order to safeguard the dignity and rights of the individual and to protect public health and the environment. **[They shall ensure that research results cannot be used towards bellicose ends.]**

*Article 15 [Article 14]*

States shall recognize the value of promoting, at various ~~appropriate levels~~ levels as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to identify ethical, social and human issues raised by research and interventions affecting the human genome.

**E. DUTIES AND RESPONSIBILITIES TOWARDS OTHERS**  
**[ DUTY OF SOLIDARITY ]**

*Article 14 [Article 15]*

States must guarantee the effectiveness of the duty of solidarity towards individuals, families and population groups that are particularly vulnerable to disease or disability linked to anomalies of a genetic character.

*[Article 16 NEW]*

**States must, as far as possible, encourage biological and genetic research undertaken in order to find a treatment for rare diseases or endemic diseases which afflict a large proportion of the world's population.]**

*Article 16 [Article 17]*

States shall undertake, with due regard for democratic principles, to foster the international dissemination of scientific knowledge concerning the human genome and to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

**F. INTERNATIONAL CO-OPERATION**  
**[ PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION ]**

*Article 17 [Article 18]*

States shall undertake to promote specific teaching and research concerning the ethical, social and human foundations and implications of biology and genetics.

*Article 18 [Article 19]*

States shall undertake to encourage ~~any~~ other forms of research, training and information conducive to raising the awareness of society [~~and each of its members~~] of ~~its~~ their responsibilities regarding the basic choices entailed by advances in biology and genetics. [**They shall also undertake to promote an open international debate, ensuring the free expression of the various shades of socio-cultural, religious and philosophical opinion.**]

<b>G. IMPLEMENTATION OF THE DECLARATION</b>
---

*Article 19 [Article 20]*

States shall undertake to ensure that the principles set out in this Declaration are respected [**and shall, by means of all appropriate measures, ensure their implementation**].

*Article 20*

~~The principles set out in this Declaration shall guide all authorities and other persons responsible for their implementation.~~

*Article 21*

States shall undertake to promote, through education, training and information, respect for the aforementioned principles, based on human dignity and human rights and to foster their recognition and effective application.

*Article 22*

The international Bioethics Committee of UNESCO shall ~~monitor observance of~~ [**help to disseminate**] the principles set out in this Declaration. ~~For this purpose, it may~~ [**shall**] make recommendations and give advice [**concerning its follow-up**].

*Article 23*

~~No provision of~~ [**Nothing in**] this Declaration may be ~~used by~~ [**interpreted as implying for**] any State, group or person [**any right to engage in any activity or to perform any act**] ~~ends~~ contrary to the principles set forth herein.

**REVISED PRELIMINARY DRAFT OF  
A UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS**

(20 December 1996)

*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 all '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 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 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 and the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958,

*Bearing in mind* 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 biological diversity of humanity shall 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 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 and individual 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. THE HUMAN GENOME

### *Article 1*

The human genome is common heritage of humanity. It underlies the fundamental unity of all members of the human family, as well as the recognition of the inherent dignity of each of its members.

### *Article 2*

- a) The genome of each individual represents a specific genetic identity.
- b) Individuals cannot be reduced to their genetic characteristics.
- c) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

### *Article 3*

The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to education, living conditions, food, state of health of each individual and in general his or her natural and social environment.

## B. RESEARCH ON THE HUMAN GENOME

### *Article 4*

- a) Research, which is necessary to the progress of knowledge, is part of the freedom of thought. Its applications, especially in biology and genetics, should relieve suffering and improve the health of individuals and the well being of humankind as a whole.
- b) Benefits from advances in biology and genetics should be made available to all, with due regard to the dignity and rights of each individual.

### *Article 5*

No research applications should be allowed to prevail over the respect for human dignity and human rights, in particular in the fields of biology and genetics.

## C. RIGHTS OF THE PERSONS CONCERNED

### *Article 6*

- a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the risks and benefits pertaining thereto and in accordance with any other regulation prescribed by national legislation in force.

b) In all cases indicated in paragraph (a) above, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, this shall be obtained from his or her representatives, guided by the person's best interest, as an individual or as a member of a given group.

c) In the particular case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.

d) Exceptions to the stipulations in the preceding paragraphs (a) to (c) may be provided for by law for reasons of public safety in a democratic society, with the purpose *inter alia* of the prevention and repression of crime.

#### *Article 7*

No one may be subjected to discrimination based on genetic characteristics that is intended to diminish or has the effect of diminishing human dignity or impairing the right to be treated equally.

#### *Article 8*

Genetic data associated with a named person and stored or processed for the purposes of research or any other purpose must be held confidential and protected against disclosure to third parties.

#### *Article 9*

Every individual has the right to a fair compensation for any injuries sustained as a direct and determining result of an intervention affecting his or her genome, in the conditions foreseen by law.

### **D. CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY**

#### *Article 10*

Researchers in the field of the human genome, because of the ethical and social implications of such research, shall do so with meticulousness, caution, intellectual honesty and integrity, both in conducting their research and in presenting and exploiting their findings.

#### *Article 11*

States shall foster the intellectual and the material conditions favourable to freedom in the conduct of research on the human genome, on the basis of the principles set out in this Declaration.

#### *Article 12*

States shall provide the framework for the free exercise of research on the human genome with due regard for democratic principles, in order to safeguard the dignity and rights of the individual and to protect public health and the environment. They shall ensure that research results cannot be used for the preparation and conduct of wars.

#### *Article 13*

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

### **E. DUTY OF SOLIDARITY**

#### *Article 14*

States shall ensure respect for the duty of solidarity towards individuals, families and population groups that are particularly vulnerable or affected by disease or disability linked to anomalies of a genetic character. To this end, they shall foster research on identification, prevention and treatment of rare diseases or endemic diseases which afflict a large proportion of the world's population.

*Article 15*

States shall undertake, with due regard for democratic principles, to foster the international dissemination of scientific knowledge concerning the human genome and to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

*Article 16*

- a) In the framework of international co-operation, States shall ensure that:
- i) research on human biology and genetics covers the special problems of developing countries;
  - ii) the capacity of those countries to carry out such research is strengthened;
  - iii) developing countries can enjoy the benefits of such research;
  - iv) the prevention of abuse and the assessment of the risks and benefits pertaining to research on the human genome are ascertained;
  - v) access to scientific knowledge in these areas is guaranteed.
- b) Relevant international organizations shall support and promote the measures taken by States for the aforementioned purposes.

**F. PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION***Article 17*

States shall undertake to promote specific teaching and research concerning the ethical, social and human basis and implications of biology and genetics.

*Article 18*

States shall undertake to encourage other forms of research, training and information conducive to raising the awareness of society and all of its members of their responsibilities regarding the basic choices entailed by advances in biology and genetics. They shall also undertake to facilitate an open international debate, ensuring the free expression of socio-cultural, religious and philosophical opinions.

**G. IMPLEMENTATION OF THE DECLARATION***Article 19*

States shall undertake to ensure that the principles set out in this Declaration are respected and shall, by means of all appropriate measures, ensure their implementation.

*Article 20*

States shall undertake to promote, through education, training and information, respect for the aforementioned principles and to foster their recognition and effective application.

*Article 21*

The International Bioethics Committee of UNESCO shall help to disseminate the principles set out in this Declaration. It shall make recommendations and give advice concerning its follow-up.

*Article 22*

Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act contrary to the principles set forth herein.

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Achévé d'imprimer en juillet 1999  
S.C.I.P.P. - Vincennes

*Imprimé en France*  
Dépôt légal : juillet 1999