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PRELIMINARY DRAFT OF A UNIVERSAL DECLARATION ON THE

HUMAN GENOME AND HUMAN RIGHTS

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The present version stems from the debate which took place at the Third Session of the International Bioethics Committee of UNESCO (IBC), held from 27 to 29 September 1995. It takes also into account the amendments proposed subsequently by the Legal Commission of the IBC.

This version will be examined by the IBC at its Fourth Session, in September 1996.

**PRELIMINARY DRAFT OF A
UNIVERSAL DECLARATION ON THE
HUMAN GENOME AND HUMAN RIGHTS**

The General Conference,

Recalling that the Preamble of UNESCO's Constitution refers to "the democratic principles of the dignity, equality and mutual respect of men", rejects "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 2 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.

C. INTERVENTIONS AFFECTING THE HUMAN GENOME

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.

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, 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.

8 August 1996

Dr Georges B Kutukdjian
Secretary-General of the IBC
Director of the Bioethics Unit
UNESCO
7 place de Fontenoy
75352 PARIS CEDEX 15 FRANCE

DRAFT UNIVERSAL DECLARATION ON THE HUMAN
GENOME AND HUMAN RIGHTS

As you know I will not be able to attend the meeting of the International Bioethics Committee in September/October 1996 in Paris. The meeting clashes with my obligations to participate in sittings of this Court.

2. I offer a few textual comments. I will then offer some general comments. I am content to accept the consensus of the IBC. Having participated in the drafting of international law in a multi-member committee, I fully realise the difficulty of securing unanimity.

Recital

3. In the closing part of the Recital, in the clause beginning "Recognising" para (b) reference is made to "eugenic practice". This expression is uncertain. In the view of some it might include pre-natal diagnosis followed by abortion. It is difficult to talk about genetic developments without addressing the issue of abortion. I realise that this is highly controversial and might slow our work. Perhaps the current phrase is as much as can be accepted, given that different minds will react in different ways to whether, in given circumstances, abortion is a "eugenic practice that runs counter to human dignity and human rights". But IBC should be aware of the fact that this phrase will be read differently by different readers.

4. Amongst the general principles, may it not be desirable to add another paragraph dealing with the minimisation and prevention of harm that could be done to an individual by misuse of genetic information. In my view this is one of the important reasons for adopting a draft declaration. It ought therefore be given a prominent position at the beginning of the document.

5. Whilst there is a solemn recollection of international conventions on human rights, it might be desirable to incorporate in a stated principle of non-discrimination, reference to international conventions on human rights.

Part A - The Human Genome

6. *Article 1:* The references to the "human genome" and "common heritage" are undefined. So far as the "human genome" is concerned, there is a range of possibilities. It could refer to the genome of each individual; the genome being sequenced for the human genome project; and the genome of the human species. I realise that consideration has been given to the problem of definition. But at least in explanatory material, we should get clear what we are talking about.

7. Secondly, the notion of "common heritage" is rather delphic. I am aware, from the writings of Professor Knoppers of how she uses the term. But I doubt that most readers would find the expression a clear one. It would be desirable that our draft should give a textual explanation of what it is really saying. The human genome in its natural form is unpatentable. If the article is attempting to state that it is ethically unacceptable to patent human genes, then it should say so explicitly. The mere fact that WIPO and other bodies have particular responsibilities (which we will wait a long time, or forever, for them to exercise) is not a reason for UNESCO failing to discharge its mandate, which is broader and focussed upon a wider remit.

8. *Article 2:*

- * I have no comment on para (a) of Article 2.
- * I am, however, concerned, at the imprecise wording of para (b) of Article 2. The words "individual's personality" are too vague, at least in the English language. I suspect that the idea behind the paragraph is the problem of biological reductionism. This has been referred to by a number of social and academic commentators, especially Professors Fox and Nelkin. Biological reductionism is the term used to describe the assumption that an individual can be reduced to his / her genetic code. My doubts about the use of the words "individual's personality" arise because those words could also refer to the effect of environmental factors. For a scientific point of view it is uncertain how far an individual can, in any case, be reduced to genetic characteristics. For this reason it might be desirable to replace the prescriptive "cannot" with "should not". Perhaps

the words "individual's personality" could be replaced by "a person's individuality".

- * Paragraph (c) of Article 2 appears, in the English text, to omit words and does not make sense as it presently stands. It is a tortology to state that everyone is to have the right to respect of one's rights.

9. *Article 3:* This article appears really to reiterate the same principle as in Article 2(b). I ask for reconsideration as to whether this article is rather in the nature of part of the Recital instead of part of the operative words of the declaration.

Part B - Research on the Human Genome

10. *Article 4:* An attempt should be made to render this article more precise. In its present draft it lacks clarity as to how far the integrity of the human species extends. Could this article be used to exclude the insertion of human genes into non-humans to create trans-genics (apparently a commonly used technique). If the value of the integrity of the individual is to be paramount over general interest in biological research, whatever the utility of such research, the control of its conduct and the limitations on its product, this should be spelt out and the conflicting opinions and needs weighed by IBC.

11. *Article 5:* This paragraph appears to be a duplication of the spirit of paragraph (a) in the Recital. It is no more than a statement of the general benefit of scientific research. It does not define the conduct of this research. It does not impose normative obligations. It therefore appears to be more correctly placed in the recital rather than in the operative part of the declaration. In any case, I question whether *all* human genetic research is "an essential activity of the mind". I also question the use of the term "rights". There is a considerable controversy about the use of this term in relation to the provision of medical services. There is even greater controversy about "claims" to future benefits from further scientific activity. There may be limitations on the right to benefit beyond those specified. These may include such considerations as the cost and availability of the advances and the competing claims of others to scarce resources. In so far as the "principle" is a broad aspiration of the ethically desirable, it would be better placed in the preamble and expressed as such. In so far as it purports to impose governing obligations commensurate with "rights", it is too broadly stated and appears somewhat naive and unrealistic. Just consider this assertion in the context of, say, the availability of new drug combinations costing \$40,000 a year to persons living with HIV.

12. *Article 6:* This is a widely accepted principle, namely that respect for the individual prevails over the interests of the researcher and the research project. It is included in most statements on human experimentation. It should be cross-referenced to such statements. It appears to repeat the rather convoluted statement in article 4.

13. *New Article:* I think it would be desirable to include in this part a new and separate article covering research. Such an article should state that research on the human genome should be governed by the international statements on human experimentation previously promulgated. This approach has been used in Australia and elsewhere to make inclusive reference to the national statement on human experimentation in guidelines which apply to new scientific endeavours. The Australian National Health and Medical Research Council's *Statement on Human Experimentation* has supplementary notes appended to it covering the particular case of gene therapy. There are also guidelines on the keeping of genetic registers. There are cross-references in the supplementary notes, referring to the basic principles in the *Statement*.

14. Such a new article, cross-referenced to the relevant international and national statements on human experimentation, would ensure that genetic research in the area of the human genome would be subject to the general research regime which includes the principles of informed consent, the monitoring of research and the scrutiny by institutional ethics committees. A weakness in the present draft is that it does not integrate our Declaration with the longstanding and now relatively developed jurisprudence on human experimentation which provides an intellectual context in which to place this new development. If there is a reason for the distinction I should like to have it explained.

Part C - Interventions Affecting the Human Genome

15. *Title:* I would prefer a different title for this part. It is unclear what is meant by the present title. In a strict sense, this part only applies, by its terms, to gene therapy techniques. However, the articles in this part may cover genetic testing and screening as well.

16. *Article 7:* The term "informed consent" tends to be culture-bound. In fact, it tends to be a Western notion grounded in perceptions of individual rights. In Australia, guidelines have been issued in relation to research into Aboriginal and Torres Strait Islanders which required group consultation and consent of elders, in addition to the consent by individuals. It is important that our Declaration should pay attention to the principles and practices of non-Western cultures. At the very least this should be referred to in explanatory documentation in order to show that we are aware of this issue. It arises most clearly in the context of the Human Genome Diversity Project but it is important to the present draft of our Declaration.

17. *Article 8:* I agree with the general spirit of this article which seeks to embody the principle of non-discrimination. However, it may have problems in its application to insurance. It is possible to interpret this article in a narrow way. This would exclude discrimination by the insurance industry on the basis of

genetic characteristics. Because this is permissible discrimination under the law of many countries, including my own, it affects neither "dignity or equality". On the other hand, this form of permissible discrimination may be interpreted as having an effect on the enjoyment of rights on the grounds of equality. In most countries, insurance cover allows such "discrimination". Many, if not most, types of insurance of individuals allows discrimination on the basis of, eg family history of heart disease, smoking practice, the presence of HIV antibodies or family history of various genetic conditions. It would be desirable that the present draft of Article 8 should be reconsidered as it affects current insurance practice. It would be highly desirable that IBC obtain assistance from the international insurance industry on how such an article could work against the background of long established insurance practice that it justified on the sharing of risks and the setting of premiums. I suspect that what is needed is a somewhat more detailed and precise provision.

18. *Article 9:* The wording of this article appears defective. It is too widely expressed. In some circumstances it may be ethically justifiable for third parties to be given access to an individual's genetic information. It may also be ethically acceptable for a person to divulge genetic information to a third party having a legitimate personal interest. Indeed, one of the main points frequently made in the literature concerning genetic information is that, of its nature, it is family oriented rather than individual oriented. Where there is a danger to the life or health of other family members, quite complex ethical considerations must be taken into account which are not reflected in the current draft of the article.

19. There are also other circumstances, outside the legitimate interests of persons of related genetics, which must be included or at least reflected in our draft. These include *bona fide* researchers dealing with material which will be anonymised for publication; criminal investigators in certain extreme circumstances and public health officials in the case of epidemics. Much greater attention must be given to the ambit of the exception to confidentiality of genetic data. The difficulties arising in this area were discussed in some detail by the report of the Shaw Committee to the House of Commons of the United Kingdom Parliament (1995). At the very least, a rider should be included on the article which permits disclosure with the consent of the data subject or by authority of law made for substantial cause. The words "stored or processed" may not cover all aspects of privacy and confidentiality. Memorised information is subject to professional rules of confidentiality; but it may not be covered by the present wording of this article.

20. *Article 10:* I draw attention to the fact that this article appears to be contrary to the notion accepted by the law of common law countries that negligence, giving rise to liability, depends upon the foreseeability of harm rather than the direct result of conduct later found to be harmful. It is arguable that in

the experimental phrase of genomic research a wider protection, such as is envisaged by the article, should be given to the individuals affected.

21. The phrase "intervention affecting" could be simply expressed as a principle of compensation for injury. Nothing more would need to be said as the injury being referred to would be sufficiently clear from the context of the other articles of the Declaration.

Part B - Rights and Obligations of Researchers

22. *Article 11:* This article would appear to require redrafting. It is possible to interpret the article as an obligation on States to allocate resources to research on the human genome. With respect, that may not be appropriate in a Declaration of this type concerned with human rights. The meaning of the words "... ensure the intellectual and material conditions" is particularly unclear. If those words mean that the State should ensure that intellectual property protection is available, that should be stated explicitly; but I am not sure that I would support it. Perhaps the use of the word "promote" rather than "ensure" would make the purpose clearer.

23. *Article 12:* It is difficult to see the relationship between a framework for research and democratic principles. There are dangers in this idea, relating to the regulation of research. The content of democratic principles is distinctly obscure and arguable. The article also appears to confuse the issues of dignity and rights of an individual with safety issues associated with public health and the general environment. Obviously, all of these issues are important and worthy of mention in the Declaration. But they should not be confused. The ethical issues of genetic manipulation should be distinguished from those of safety. As presently drafted, the article conflates the two issues which should be separated. In dealing with the aspect of dignity and rights, it would be appropriate to refer to the dignity and rights of cultural groups as well as of individuals.

24. *Article 13:* The expectation that researchers will be meticulous, cautious and intellectually honest really goes without saying. Codes of ethics are devised to ensure that this will be done. A real problem faced by geneticists is conflict of interest between their general obligation to scientific knowledge and its advancement (on the one hand) and commercial interest and advantage (on the other). It would be desirable that the declaration should address the ethical responsibility to avoid conflicts of interest and duty. This does not appear to be mentioned in the present draft. It deserves mention.

Part E - Duties and Responsibilities Towards Others

25. *Article 14:* The notion of "solidarity" towards individuals, families etc would seem to be somewhat inconsistent with the present draft of the duty of confidentiality propounded in such

absolute terms in Article 9. The difficulties of reconciling such conflicting duties should be resolved or at least acknowledged in the explanatory material.

26. *Article 15:* This is an important article. But it does not appear to belong in this part of the Declaration. The article would be better placed in a separate part titled "Scrutiny by Independent Ethics Committees". I agree with the inclusion of the word "independent". This is an essential pre-requisite of an effective ethics committee.

Part F - International Cooperation

27. *Article 16:* No comment.

28. *Article 17:* This article would appear to be more naturally placed in the research section, Part D.

29. *Article 18:* I endorse this article most strongly. I cannot over-emphasise its importance. I consider that the educational aspect of the Draft Declaration should be given greater prominence. Perhaps it warrants a separate Part. A statement is required, of a normative character, eg "All States shall undertake to provide general and particular education to society ... etc".

Part G - Implementation of the Declaration

30. *Articles 19-23:* There are no problems with this part.

General

31. If I were present at the IBC meeting, I would be laying emphasis upon the need to reconsider the format of the declaration so as to draw a sharp distinction between matters apt for the Recital and matters apt for the normative or substantive parts of the Declaration. My feeling is that the present draft does not always keep the distinction clear. It will be important to support the statements of principles with explanatory commentaries and illustrations. In this respect I commend the format used by CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (1993).

32. I would also be stressing the fact that the Draft does not make adequate reference to a great body of ethical statements concerning biomedical research and human experimentation dating from the *Declaration of Helsinki*. Many nations, including my own, have accepted the principles in this Declaration. Many have applied those principles to the codes of conduct for biomedical research, including genomic research. Because the current draft of the Declaration lacks adequate cross-referencing to this large body of jurisprudence of wide global acceptance, there is a serious defect that the current Declaration appears to exist *in vacuo*. In its next draft it should be integrated with this respectable and widely accepted body of jurisprudence and principle. On the same theme, some cross-referencing to the

institutional ethics committees of various nations would be appropriate, if not in the Draft Declaration itself, at least in the supporting documentation. We should not pretend that UNESCO is coming to this issue as a blank page. Important work has been done by national and institutional ethics committees which UNESCO should acknowledge.

33. It is impossible for me to attend meetings of the Committee which clash with my obligations to sit in Court. In fixing the agenda for the meeting in 1997, could I ask that it be kept in mind that I will be obliged to sit 22-30 September; 1-3 and 20-24 October 1997. I realise that such a Committee with so many busy members cannot suit the convenience of particular members. However, if the next meeting avoids the foregoing dates, I will strive to attend.

34. As the Director-General has asked me to present the Draft Declaration to the Annual Conference of the Human Genome Organisation which is taking place in Canberra, Australia, 17-18 October 1996, and as I have agreed to do this, I would ask that you send me, immediately following the end of the IBC consultation in early October, a note on the discussions, so that I can give the HUGO meeting an up-to-date briefing on behalf of the Director-General.

35. If you think it appropriate, I would invite you to circulate this commentary with the papers for the upcoming meeting.

MICHAEL KIRBY