Meeting of Government Experts
Responsible for Finalizing the Draft International Declaration on Human Genetic Data

UNESCO House, 25 to 27, 28 or 29 June 2003
(Room XI, Fontenoy building)

PRELIMINARY DRAFT OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

This Preliminary Draft of the International Declaration on Human Genetic Data has been elaborated by the Drafting Group of the International Bioethics Committee (IBC) during its six meetings held in 2002-2003. It was reviewed by the IBC at its Ninth and Tenth Sessions (Montreal, 26-28 November 2002 and Paris, 12-14 May 2003), taking into account the observations formulated during the Public Hearings Day (Monte-Carlo, Monaco, 28 February 2003), the comments made at the 166th Session of the Executive Board of UNESCO (UNESCO House, 11 April 2003), as well as the replies received to the Questionnaire concerning an Outline of this declaration.

Division of the Ethics of Science and Technology

(SHS-2003/CONF.203/CLD.3)
The General Conference,


Recalling more particularly the Universal Declaration on the Human Genome and Human Rights which it adopted, unanimously and by acclamation, on 11 November 1997 and which was endorsed by the United Nations General Assembly on 9 December 1998, and the Guidelines for the implementation of the Universal Declaration on the Human Genome and Human Rights which it endorsed on 16 November 1999 by 30 C/Resolution 23,

Welcoming the broad public interest worldwide in the Universal Declaration on the Human Genome and Human Rights, the firm support it has received from the international community and its impact in Member States drawing upon it for their legislation, regulations, norms and standards, and ethical codes of conduct and guidelines,

Bearing in mind the international and regional instruments, national laws, regulations and ethical texts and the statements adopted by international non-governmental organizations relating to the protection of human rights and fundamental freedoms and to respect for human dignity as regards the collection, processing, use and storage of scientific data, as well as of medical data and personal data,

Recognizing that human genetic data have a special status on account of their sensitive nature since they provide both medical and personal information that is relevant throughout life and may contain information on the family, extending over generations or, in some circumstances, on the group to which the person concerned belongs,

Considering that the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications, and for the use of such data for non-medical purposes, in particular, civil and criminal proceedings,

Aware nevertheless that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms, and respect for human dignity,

Reaffirming the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, both freedom of research and protection of privacy, which must underlie the collection, processing, use and storage of human genetic data,

Proclaims the principles that follow and adopts the present Declaration.
A. USE OF TERMS

Article 1: Use of Terms

a) For the purposes of this Declaration, the terms used have the following meanings,

i) Human genetic data: Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis.

ii) Consent: An act by which a person gives his or her agreement to a procedure.

iii) Data linked to an identifiable person: Data that contain information, such as name, birth date and address, by which the person from whom the data were derived can be identified.

iv) Data unlinked to an identifiable person: Data that are not linked to an identifiable person, through destruction of all information about the person who provided the sample or through the replacement of the name of that person with a code.

v) Genetic testing: A diagnostic procedure aimed at detecting a genetic pathology, or genetic characteristics that predispose a person to a pathology, or a genetic mutation that could be transmitted to descendants.

vi) Genetic screening: Large-scale genetic testing of persons who belong to a given age group or of a group of persons who are presumed to be genetically vulnerable.

vii) Genetic counselling: A procedure to inform about genetic risks and to explain the implications of possible findings of genetic testing or screening and, if necessary, to assist a person in the long-term handling of the consequences. It takes place before and after genetic testing and screening.

viii) Cross-matching: Matching of information about an individual or a group contained in various data files set up for different purposes.

b) The footnotes in this Declaration are an integral part of the Declaration.

B. GENERAL PROVISIONS

Article 2: Aims and Scope

a) The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms, in the collection, processing, use and storage of human genetic data and of the biological samples(1) from which they are derived; to set out the principles which should guide States in the formulation of their legislation on these issues; and to form the basis for guidelines of good practices in these areas for concerned institutions and individuals.

b) This Declaration shall apply to human genetic data as well as to data that are derived therefrom, for example proteomic data, and, where applicable, to the biological samples from which human genetic data are derived, referred to hereinafter as “biological samples”.

1. Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual.
Article 3: Person’s Identity
Each individual has a characteristic genetic make-up. Nevertheless, a person’s identity should not be reduced to genetic characteristics, since it is made-up of complex educational, environmental and personal factors and is shaped by emotional, social, spiritual and cultural bonds with others.

Article 4: Special Status
a) Human genetic data have a special status, because:
   (i) they are often predictive of genetic predispositions of life-long relevance to the person concerned;
   (ii) they may have a significant impact on the family, extending over generations, and in some instances on the whole group to which the person concerned belongs;
   (iii) they contain information, the significance of which is not necessarily known at the time of the collection of the biological samples.

b) Due consideration is to be given to human genetic data and to the biological samples when they have particular cultural significance for persons or groups.

Article 5: Purposes
Human genetic data may be collected, processed, used and stored only for the purposes of:
   (i) diagnosis and health care;
   (ii) medical and other scientific research, including population-based genetic studies and epidemiological or anthropological studies, collectively referred to hereinafter as “medical and scientific research”;
   (iii) forensic medicine;
   (iv) civil or criminal proceedings;
   (v) and any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and international human rights law.

Article 6: Procedures
a) Human genetic data shall be collected, processed, used and stored on the basis of transparent procedures. States should endeavour to involve society as a whole in the decision-making process concerning the collection, processing, use and storage of human genetic data and the evaluation of their management, in particular in the case of large-scale population-based genetic studies. This decision-making process, which may benefit from international experience, shall ensure the free expression of various viewpoints.

b) Independent, multidisciplinary and pluralist ethics committees should be established, in accordance with Article 16 of the Universal Declaration on the Human Genome and Human Rights. Ethics committees at national level shall be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, and of biological samples and ethics committees at institutional or local levels shall be consulted with regard to their application to specific research projects. Where two or more States are involved, the ethics committees in the States concerned shall be consulted and the review of these questions at the appropriate level shall be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the concerned States.
c) Clear, balanced and comprehensive information shall be provided to the person whose consent is sought. This information shall specify the purpose for which human genetic data and the biological samples are being collected and the reason for their processing and possible storage. This information shall also indicate that the person concerned can withdraw his or her consent, and where applicable, that he or she is participating as a member of a group.

Article 7: Non-discrimination and Non-stigmatisation

a) Human genetic data shall not be used for discriminatory purposes nor in a way that may lead to the stigmatisation of an individual, a family or a group.

b) In this regard, particular attention shall be paid to the findings of population-based genetic studies\(^2\) and behavioural genetic studies\(^3\) and their interpretations.

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**C. COLLECTION**

Article 8: Consent

a) At the time of collection of human genetic data and of the biological samples, through either invasive\(^4\) or non-invasive\(^5\) procedures and by either public or private institutions, prior, free, informed and express consent of the person concerned shall be required in writing, except in the case of illiterate persons. Limitations on this principle of consent shall only be prescribed for compelling reasons by national law or regulation, consistent with international human rights law.

b) When in accordance with national law or regulation a person lacks the capacity to consent, legal authorization, which shall be prior, free, informed and express, shall be obtained, regardless of the purpose, in accordance with this national law or regulation and having regard to the best interest of the person concerned, especially in the case of persons with mental disabilities.

c) In the case of children, they will be consulted, in as much as they can understand the issues involved. The outcome of this consultation shall be confirmed by the prior, free, informed and express consent of their legal representative designated by the national law or regulation and having regard to their best interest.

Article 9: Withdrawal of Consent

When medical and scientific research is the purpose for collecting human genetic data, consent may be withdrawn by the person concerned unless such data are unlinked to an identifiable person. Withdrawal of consent shall entail neither a disadvantage nor a penalty for the person concerned. In case of withdrawal of consent, the data as well as the biological samples shall either be returned to the person concerned or destroyed.

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2. A study which aims at understanding the nature and extent of genetic variation among individuals within a group and/or between individuals across different groups.

3. A study that aims at establishing possible connections between genetic characteristics and behaviour.

4. Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe.

5. Biological sampling using a method which does not involve intrusion into the human body, such as oral smears.
Article 10: The Right to Decide whether or not to be Informed about Research Results

When human genetic data are collected for medical and scientific research purposes, the information provided at the time of consent shall indicate that the person concerned has the right to decide whether or not to be informed of the results. This shall not apply to research on data unlinked to identifiable persons and which do not lead to individual findings concerning the persons who have participated in such research.

Article 11: Genetic Counselling

When human genetic data are collected for diagnostic and health care purposes, or for medical and scientific research purposes, genetic counselling shall be offered without being mandatory, in all instances and at all stages of testing, where the results of the testing or of the research could have an impact on the individual or the family, extending over generations. Genetic counsellors shall be independent and genetic counselling shall be non-directive, culturally adapted and having regard to the best interest of the person concerned.

Article 12: Collection of Biological Samples for Forensic Purposes or in Civil and Criminal Proceedings

When human genetic data are collected for the purposes of forensic medicine or in civil or criminal proceedings, requests for the collection of biological samples, in vivo or post mortem, shall be made in accordance with national law or regulation, consistent with international human rights law. In the case of parentage testing, the decision shall be taken having regard to the best interest of the child and family.

D. PROCESSING

Article 13: Access

Everyone shall have access at any stage of the processing of human genetic data to his or her data, unless such data are unlinked to the person concerned.

Article 14: Confidentiality

a) Confidentiality of human genetic data linked to an identifiable person, a family or a group shall be guaranteed in accordance with national law or regulation and in conformity with international human rights law.

b) Human genetic data linked to an identifiable person shall not be disclosed or made accessible to third parties, such as employers and insurers, unless it is decided by national law or regulation in the public interest and is consistent with international human rights law.

c) Human genetic data collected for medical and scientific research purposes, if justified by the needs of the research, can be linked to an identifiable person, provided that the confidentiality of the data concerned is guaranteed.

d) Even when such data are unlinked to an identifiable person, the necessary precautions shall be taken to ensure the security of the data, with due regard to the exercise and observance of human rights, fundamental freedoms and human dignity.
Article 15: Accuracy, Reliability, Quality and Security

The persons and entities responsible for the processing of human genetic data shall take the necessary measures to ensure the accuracy, reliability, quality and security of the human genetic data. They shall exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, particularly in the field of behavioural genetics, in view of their ethical, legal and social implications.

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E. USE

Article 16: Change of Purpose or of Medical and Scientific Research Objective

a) Human genetic data and the biological samples collected for one of the purposes set out in Article 5 or a given medical and scientific research objective shall not be used for a different purpose or medical and scientific research objective, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or it is decided by national law or regulation that the use proposed is in the public interest and is consistent with international human rights law. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) shall apply mutatis mutandis.

b) Whenever the prior, free, informed and express consent cannot be obtained or in the case of data unlinked to an identifiable person, the provisions of Article 6(b) shall apply mutatis mutandis.

Article 17: Stored Biological Samples

a) Stored biological samples (6) may be used to produce human genetic data with the free, informed and express consent of the person concerned. However, national law or regulation may provide that if such data have significance for medical and scientific research or public health purposes, they may be used for those purposes, following the consultation procedures set out in Article 6(b) or after consultation of the competent organ in the State concerned, even in the absence of consent of the person concerned, or in the case of deceased persons.

b) The provisions of Article 12 shall apply mutatis mutandis to stored biological samples used to produce human genetic data for forensic medicine or in civil and criminal proceedings.

Article 18: Circulation and International Co-operation

a) States should establish, in accordance with national law or regulation, a system for regulation of the cross-border flow of human genetic data and of the biological samples, so as to foster international medical and scientific cooperation and ensure fair access to this data. Such a system shall ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

b) Researchers shall endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters, and, subject to the provisions of Article 14, shall encourage the free circulation of human genetic data, in order to foster the sharing of scientific knowledge, provided that the principles set out in this Declaration are observed by the parties concerned. Towards this goal, they shall also endeavour to publish in due course the results of their research.

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6. A biological sample which has been stored with or without the identification of the living or dead person who provided the sample.
Article 19: Sharing of Benefits

Benefits resulting from the use of human genetic data collected for medical and scientific research shall be shared with the society as a whole and the international community. They may take any of the following forms:

i) special assistance to the persons and groups that have taken part in the research;
ii) access to medical care;
iii) provision of facilities for new treatment or drugs stemming from the research;
iv) support for health services;
v) capacity-building facilities for research purposes;
vi) any other form consistent with the principles set out in this Declaration.

F. STORAGE

Article 20: Monitoring and Management System

A system for the monitoring and management of human genetic data, based on the principles of independence, multidisciplinarity, pluralism and transparency as well as the principles set out in this Declaration, should be established in each country. This system should deal with the nature and purposes of the storage of this data as well as with the question of any proprietary or other regime of human genetic data and shall ensure the consistency of the application of guidelines and procedures set out in national law or regulation as well as in national guidelines or by ethics committees at different levels and that the storage of computerized or manually processed human genetic data enjoys adequate protection, having regard to the special status of this data as set out in Article 4 of this Declaration.

Article 21: Destruction

a) If the person concerned so requests, his or her genetic data and the biological samples collected for diagnostic and health care purposes and for medical and research purposes shall be destroyed, unless such data are unlinked to the person concerned or a national law or regulation makes such provision for their preservation as necessary in the interests of public health, public order or national security.

b) Human genetic data and the biological samples collected from a suspect in the course of a criminal investigation shall be destroyed if the person investigated is either not charged with an offence or is found not guilty of the offence in respect of which the genetic data were collected. Only human genetic data of persons found guilty of a crime by virtue of a final judgment may be conserved.

c) Human genetic data and the biological samples shall be available for forensic purposes and civil proceedings only for as long as they are required for those proceedings.

Article 22: Cross-Matching

Human genetic data stored for diagnostic and health care purposes and for medical and scientific research purposes shall not be cross-matched with data stored in civil or criminal proceedings.
G. PROMOTION AND IMPLEMENTATION

Article 23: Implementation

a) States should adopt measures, whether of a legislative, administrative or other character, to give effect through laws or regulations to the principles set out in this Declaration. Such measures should be supported by action in the sphere of education, training and public information.

b) In the framework of international co-operation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build-up their capacity to participate in the sharing of scientific knowledge concerning human genetic data and of the related know-how.

Article 24: Ethics Education, Training and Information

In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 25: Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees shall be responsible of its monitoring and for the evaluation of its implementation, inter alia on the basis of reports provided by States. The two Committees shall be responsible in particular of the formulation of any opinion or proposal likely to further the effectiveness of this Declaration.

Article 26: Follow-up Action by UNESCO

UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of life sciences and their applications through technologies, based on the respect of human dignity and the exercise and observance of human rights and fundamental freedoms.

Article 27: Denial of Acts Contrary to Human Rights, Fundamental Freedoms and Human Dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.