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REVISED OUTLINE OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

This Revised Outline of the International Declaration on Human Genetic Data was produced following a preliminary review by the International Bioethics Committee (IBC) at its Ninth Session (Montreal, Canada, 26-28 November 2002) and on the basis of the deliberations of the 4th meeting of the Drafting Group of the IBC (Montreal, Canada, 29 November 2002).

The General Conference,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

Recalling more particularly the Universal Declaration on the Human Genome and Human Rights that 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, or 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 collection, processing, use and storage of scientific data, as well as of medical data, personal data and sensitive 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, including descendants 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 science and medicine and for the use of such data for non-medical, in particular judicial, purposes,

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, 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. GENERAL PROVISIONS


Article 1: Meaning and scope


Human genetic data are information about heritable characteristics of individuals obtained by analysis of deoxyribonucleic acid (DNA) sequences or by other means. This Declaration shall apply to human genetic data as well as to data that are derived therefrom.

Article 2: 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 determined by complex educational and other environmental factors as well as by emotional, social and cultural bonds with others. 

Article 3: Special Status

a) Human genetic data constitutes a special category of information because it provides scientific, medical and personal information, and it may have both sensitive components and lifelong relevance in relation to genetic predispositions. Moreover, this information 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. 


b) Human genetic data and the biological samples used to produce them may have particular cultural significance for persons or groups and for this reason require special consideration and respect. 

Article 4: Purposes


Human genetic data may only be collected, processed, used and stored for purposes of: diagnosis and health care, medical and other scientific research, including epidemiological studies, forensic medicine, judicial purposes in civil or criminal proceedings, and any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and international human rights law.


Article 5: Procedures

a) Human genetic data shall be collected, processed, used and stored according to transparent procedures providing for the informed participation by society as a whole. To that end, on the basis of concerted action in the sphere of education and information, States shall endeavour to involve society as a whole in decision-making 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 studies. Such a debate will be open to international participation and will ensure the free expression of various viewpoints.

b) Independent, multidisciplinary and pluralist ethics committees shall be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, including the biological samples used to produce them. In case two or more countries are involved, the ethics committees of the countries concerned shall be consulted and the review of these questions shall be based on the principles set forth in this Declaration and on the ethical and legal standards adopted by States. 

Article 6: 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) Particular attention shall be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations. 

B. COLLECTION

Article 7: Consent

a) Prior, free, informed and express consent shall be required for the collection of human genetic data, either through invasive or non-invasive procedures and whether public or private institutions carry them out.

b) When in accordance with national legislation a person is not in a position to consent to the taking of samples for the production of human genetic data, prior, free, informed and express consent or legal authorization shall, regardless of the purpose, be obtained in accordance with this law or the national regulation and having regard to the best interest of the person concerned, especially in the case of children and handicapped persons 


Article 8: Withdrawal of Consent

In the case of medical and scientific research, consent may be withdrawn by a person within the time limits that shall be specified at the time of consent, unless such data are irretrievably unlinked to an identifiable person. Withdrawal of consent will entail neither a disadvantage nor a penalty.

Article 9: The Right to Decide whether or not to be Informed

When human genetic data are collected for medical and other scientific research purposes, including epidemiological and population-based genetic studies, or for genetic screening, consent shall also include the choice to be made by a person as to whether or not to be informed of the results of the research or of the screening test.

Article 10: Genetic Counselling

When human genetic data are collected for individual diagnostic purposes or in the case of genetic screening, genetic counselling shall be made available, without being mandatory, in all instances where the results of the testing could have an impact on the individual or the family, extending over generations. 

Article 11: Collection of Samples in vivo or post mortem

When human genetic data are collected for the purposes of forensic medicine or for judicial purposes in civil or criminal proceedings, requests for the collection of samples, in vivo or post mortem, shall be made only on the basis of a judicial decision, 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.

C. PROCESSING

Article 12: Access

Everyone shall have access at any stage to his or her genetic data, unless such data are irretrievably unlinked to an identifiable person.

Article 13: Confidentiality

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

b) Human genetic data linked to an identifiable person shall not be disclosed or accessible to third parties, in particular employers, insurance companies or educational institutions, except in cases provided for by national legislation or regulations and subject to the consent of the person concerned, and in compliance with international human rights law.

Article 14: Unlinking of human genetic data

Human genetic data collected for the purposes of scientific research shall be unlinked to an identifiable person. If this unlinking is retrievable, the necessary precautions shall be taken to ensure the confidentiality of the data with respect to third parties with due regard to the exercise and observance of human rights, fundamental freedoms and human dignity.

Article 15: Accuracy, Reliability, Quality and Security


The accuracy, reliability, quality and security of human genetic data shall be ensured. Relevant professional bodies shall exercise rigour, caution, intellectual honesty and integrity in the processing and interpretation of human genetic data, particularly in the field of behavioural genetics, in view of their ethical and legal implications.

D. USE

Article 16: Change of Purpose

Human genetic data collected for a specific purpose shall not be used for a different purpose, unless the prior, free, informed and express consent of the person concerned is obtained or it is decided by authority of law.

Article 17: Archived Samples

Archived samples may be used to produce human genetic data with the free, informed and express consent of the person concerned. However, if such data have significance for medical and other scientific research or public health purposes, it may be used for those purposes, in accordance with the provisions under article 5(b), even in the absence of consent of a person. Such data shall then be made irretrievably unlinked to an identifiable person. 

Article 18: Free Circulation

The free circulation of irretrievably unlinked human genetic data, including data derived from population-based genetic studies, shall be encouraged among researchers who have established cooperative relationships based on mutual respect with regard to scientific and ethical matters, in order to foster the sharing of scientific knowledge, provided that the principles set forth in this Declaration are observed by the parties concerned.

Article 19: Cross-border Flow

The cross-border flow of human genetic data by the private or public sector, shall be regulated, in accordance with national legislation and so as to foster international cooperation and ensure fair access to human genetic data. Such regulation shall also ensure that the receiving country guarantees equivalent levels of protection in accordance with the principles set forth in this Declaration.

Article 20: Sharing of Benefits

Benefits resulting from the use of human genetic data collected for medical and scientific research, including population-based genetic studies, shall be shared with the international community as a whole and may take any of the following forms:

- special assistance to the persons and groups that have taken part in the research;
- access to medical care;
- provision of facilities for new treatment or drugs stemming from the research;
- support for health services;
- any other form consistent with the principles of this Declaration.



E. STORAGE

Article 21: Monitoring and Management System

A monitoring and management system of human genetic data, based on the principles of independence, multidisciplinary, pluralism and transparency as well as the principles set forth in this Declaration, shall be established in each country. This system, which will also deal with the ownership regime of human genetic data, shall ensure the consistency of the guidelines and procedures set out by ethical 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 human genetic data as set forth in Article 3 of this Declaration.

Article 22: Destruction

- a) Human genetic data collected in the course of a criminal investigation shall not be retained if the person investigated is either not charged with an offence or is found not guilty of the offence in respect to 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.
- b) Human genetic data shall only be available for civil proceedings for as long as they are required for those proceedings.

Article 23: Cross-Linking

Human genetic data stored for one of the purposes set forth in Article 3 of this Declaration may be cross-linked, on condition that they have been collected for the same purpose. Human genetic data stored for health care and diagnostic purposes and for medical and other scientific research purposes shall not be cross-linked with data stored for judicial purposes in civil or criminal proceedings.

F. PROMOTION AND IMPLEMENTATION

Article 24: Transposition into Domestic Law

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

Article 25: Teaching, training and information

In order to promote and enforce the principles contained in this Declaration, States shall endeavour to foster teaching and training at all levels and all forms of education as well as encourage information programmes addressed to target audiences and the public at large.

Article 26: Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) will participate in the implementation of this Declaration and the dissemination of the principles set forth therein. The two Committees will be responsible, on a collaborative basis, for monitoring its implementation, with particular reference to the formulation of any opinion or proposal likely to further its effectiveness.

Article 27: Interpretation

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 forth in this Declaration.