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*International Bioethics
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OUTLINE OF THE INTERNATIONAL INSTRUMENT ON HUMAN GENETIC DATA

Division of the Ethics of Science and Technology

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 or 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 and processing of human genetic data is 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 may hold potential dangers for the protection 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. AIM AND SCOPE

Article 1: Person's Identity

Individuals have a unique genetic make-up. Nevertheless, their identity has an essentially symbolic dimension which cannot be reduced to their genetic characteristics. A person's identity is made up of emotional, social and cultural bonds with his or her family and group, as well as with environment, both physical and human. 

Article 2: Special Status

a) Human genetic information based on genetic sequences and on the structure of the genome constitute a special category of data because it provides scientific, medical and personal information, both sensitive and of lifelong relevance, especially in relation to genetic predispositions. Moreover, this information may have a significant impact on the family and in some instances on the whole group to which the person concerned belongs. 


b) The cultural importance and the individual purport of the collection, processing, use and storage of human genetic data for the persons concerned shall be taken into account by professional bodies concerned, and by the bodies in charge of managing the data in question. 

Article 3: Purposes


Human genetic data shall be collected, processed, used and stored for the following purposes: medical and scientific research; health care; forensic medicine, and judicial purposes in civil or criminal proceedings, under conditions provided for by law and consistent with international human rights law.

Article 4: 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, States shall endeavour, on the basis of concerted action in the sphere of education and information, to involve society as a whole in decision-making concerning both the collection, processing, use and storage of human genetic data and the management of their evaluation, in particular where whole populations are concerned. Such a debate will be open to international dimensions and will ensure the free expression of various viewpoints.

b) Independent, multidisciplinary and pluralist ethics committees  have to be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data. 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 5: Protection

Human genetic data, in their different components, shall be protected by appropriate legislation and regulations in particular so as to avoid any stigmatization of a person, family or group and any discrimination against them. 

B. COLLECTION

Article 6: 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.
- 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.

Article 7: Withdrawal of Consent

In the case of medical and scientific research, the person concerned may withdraw consent within the time limits that have been specified and on condition that the genetic data in question have not been irreversibly anonymized. He or she shall neither be disadvantaged nor penalized as a consequence of such withdrawal of consent.

Article 8: The Right to Decide whether or not to be Informed

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

Article 9: Genetic Counselling

When human genetic data are collected for the purpose of health care, in addition to the prior, free, informed and express consent of the person concerned, genetic counselling shall be offered for any genetic testing that could have a [serious] impact on the individual or the family.

Article 10: 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 the procedures of 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 11: Accuracy, Reliability, Quality and Security

Professional bodies concerned with and the bodies responsible for the processing of human genetic data are duty bound to ensure the accuracy, reliability, quality and security of such data. Such bodies must ensure rigour, caution, intellectual honesty and integrity in the processing and interpretation of human genetic data, particularly that which comes within the field of behavioural genetics, in view of their ethical and legal implications, particularly with regard to respect for human rights, fundamental freedoms and human dignity.

Article 12: Anonymization

In the case of human genetic data collected for the purposes of scientific research, including population-based genetic studies, the professional bodies concerned with and the bodies responsible for the processing of the data in question shall ensure that the data concerned have been anonymized. If anonymization is reversible, they shall ensure that the necessary precautions are taken to ensure the confidentiality of the data with respect to third parties with due regard to respect for human rights, fundamental freedoms and human dignity.

Article 13: Confidentiality with respect to Third Parties

The professional bodies concerned with and the bodies responsible for processing of the genetic data associated with an identifiable person, a family or a group, shall ensure the confidentiality of the data in question with respect to third parties in accordance with national legislation or regulations and in conformity with international human rights law.

D. USE

Article 14: Non-discrimination and Non-stigmatization

Human genetic data shall not be used for discriminatory ends or in such a manner as to stigmatize an individual, a family or a group. Particular attention shall be paid to the findings of behavioural genetic studies and their interpretation.

Article 15: Change of Purpose

Human genetic data collected for one of the purposes set forth in Article 3 may be used for another purpose, provided that the prior, free, informed and express consent of the person concerned is obtained again.

Article 16: Accessibility

Genetic data associated with an identifiable person, a family or a group shall not be 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 17: Transmission


In the case of human genetic data collected for medical and scientific research and health care, researchers or doctors may only transmit them to a body responsible for human genetic data, even if they have been irreversibly anonymized, with the prior, free, informed and express consent of the person(s) concerned and specifying, as far as possible, the purposes for which they are intended and the conditions relating to their transmission.

Article 18: 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 persons and groups that have taken part in them.



Article 19: Samples taken for Health Care Purposes or Archived Samples

Human genetic data deriving from samples taken for health care purposes or from archived samples shall be used only with the free, informed and express consent of the person(s) concerned. However, if they are of undeniable interest for medical and scientific research or public health, they may be used for that purpose, even in the absence of the consent of the person(s) concerned. Such data shall then be irreversibly anonymized. 

Article 20: Free Circulation

The free circulation of anonymized 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 21: Crossborder Flow

The crossborder flow of human genetic data which have been collected, by the private or public sector, for the purposes set forth in Article 3 of this Declaration shall be regulated in such a way as to foster international cooperation and ensure fair access to human genetic data. Such regulation shall also aim to ensure that the country receiving human genetic data guarantees its protection in accordance with international human rights law and the principles set forth in this Declaration.

E. STORAGE

Article 22: Management System

A system for the management of human genetic data shall be established in each country, in the framework of the protection of human rights and fundamental freedoms and respect for human dignity, to ensure 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 2 of this Declaration. Based on the principles of independence, multidisciplinary and pluralism, the management system in question shall draw on the principles set forth in this Declaration [and shall establish the framework for the recognition of national sovereignty over genetic resources].

Article 23: Destruction

a) Human genetic data collected in the course of a criminal investigation shall not be retained if that person is either not charged with an offence or is found not guilty of the offence in respect to which the genetic data was collected. Only human genetic data of persons found guilty of a violent crime by virtue of a final judgement may be conserved permanently.

b) Human genetic data shall only be available for civil proceedings for as long as they are required for those proceedings.

Article 24: 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 collected for medical and scientific research or health care shall not be cross-linked with data collected for judicial purposes in civil or criminal proceedings.

F. PROMOTION AND IMPLEMENTATION

Article 25: Transposition into Domestic Law

States shall adopt the 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 26: Roles of the IBC and the IGBC

The International Bioethics Committee and the Intergovernmental Bioethics Committee will participate in the implementation of this Declaration and the dissemination of the principles set forth. 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.