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PROVISIONAL PRELIMINARY DRAFT OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

This Provisional Preliminary Draft of the International Declaration on Human Genetic Data has been elaborated by the Drafting Group of the International Bioethics Committee (IBC) for consideration by the IBC at its Tenth session (UNESCO House, 12-14 May 2003). It includes the proposals made by the IBC at its Ninth Session (Montreal, Canada, 26-28 November 2002) and the observations formulated during the Public Hearings Day (Monte-Carlo, Monaco, 28 February 2003). In addition, it takes into account the comments made at the 166th Session of the Executive Board of UNESCO (UNESCO House, 11 April 2003), and it also takes stock of the replies received to the Questionnaire concerning an Outline of this declaration.

Division of the Ethics of Science and Technology

The General Conference,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, 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 ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, 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 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, 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 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, 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. DEFINITIONS

Article 1: Definitions

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

- a) *Human genetic data*: Information about heritable characteristics of individuals obtained by analysis of deoxyribonucleic acid (DNA) sequences or by other scientific analysis.
- b) *Human Genome*: The complete genetic heritage of the human species, embodied in the DNA contained in the nucleus of each human cell.
- c) *Deoxyribonucleic acid (DNA)*: The molecule that constitutes the genetic material. It is composed of basic elements (called A, G, C and T). The sequence of these elements provides the information on all heritable characteristics.
- d) *Biological sample*: Any cell (for example blood, skin and bone cells) with a nucleus that contains the characteristic genetic make-up of an individual.
- e) *Archived biological sample*: A biological sample which has been stored with or without the identification of the living or dead person who provided the sample.
- f) *Invasive procedure*: Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe.
- g) *Non-invasive procedure*: Biological sampling using a method which does not involve intrusion into the human body.
- h) *Genetic predisposition*: Genetic factors which increase the possibility of a disease or a pathology.
- i) *Population-based genetic study*: 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.
- j) *Behavioural genetic study*: A study that aims at establishing possible connections between genetic characteristics and behaviour.
- k) *Consent*: An act by which a person gives his or her agreement to a clinical diagnosis or treatment or agrees to take part in research.
- l) *Data linked to an identifiable person*: Data that contain information, such as name and address, by which the person from whom the data were derived can be identified.
- m) *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. In the latter case the unlinking could be reversed through breaking of the code.
- n) *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.
- o) *Parentage testing*: A genetic test enabling the identification of the biological parent(s) of a child.
- p) *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.
- q) *Genetic counselling*: A procedure 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.
- r) *Cross-border flow*: The transmission of data beyond national borders.
- s) *Cross-matching*: Matching of information about an individual or a group contained in various data files set up for different purposes.

B. GENERAL PROVISIONS

Article 2: Scope

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

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 up by emotional, social 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 in accordance with transparent procedures. 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 genetic studies. This decision-making, 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, and shall be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic

data, as well as the biological samples. Where 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 out in this Declaration and on the ethical and legal standards adopted by 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, as defined in Article 5, 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 and behavioural genetic studies and their interpretations.

C. COLLECTION

Article 8: Consent

a) At the time of collection of human genetic data and of the biological samples, through either invasive or non-invasive procedures and by either public or private institutions, prior, free, informed and express consent of the person concerned shall be required.

b) When in accordance with national law or regulation a person lacks the capacity to consent, prior, free, informed and express consent or legal authorization 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 children and mentally disabled persons.

Article 9: Withdrawal of Consent

When human genetic data are collected for medical and scientific research purposes, 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.

Article 10: The Right to Decide whether or not to be Informed

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.

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 made available, 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 and 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 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.

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, except in cases provided for by national law or regulation and in conformity 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.
- 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 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 and legal implications.

E. USE

Article 16: Change of Purpose

Human genetic data and the biological samples collected for one of the purposes set out in Article 5 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 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) shall apply *mutatis mutandis*.

Article 17: Archived Biological Samples

- a) Archived biological 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 scientific research or public health purposes, they may be used for those purposes, in accordance with the consultation procedures set out in article 6(b), even in the absence of consent of the person concerned.
- b) The provisions of Article 12 shall apply *mutatis mutandis* to archived 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 shall 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 cooperation and ensure fair access to this data. Such a system shall ensure that the receiving party provides 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.

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) 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, multidisciplinary, pluralism and transparency as well as the principles set out in this Declaration, shall be established in each country. This system, which shall also deal with the question of any proprietary or other regime of human genetic data, shall ensure the consistency of the guidelines and procedures set out in national law or regulation or by ethics committees 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 3 of this Declaration.

Article 21: Destruction

- a) If the person concerned so requests, human 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.
- b) Human genetic data and the biological samples collected 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 shall 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 shall be supported by action in the sphere of education, training and public information.
- b) In the framework of international co-operation, States shall 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 and enforce the principles set out in this Declaration, States shall endeavour to foster all forms of ethics education and training at all levels as well as encourage information and knowledge dissemination programmes about human genetic data addressed to target audiences and the public at large. In this regard, States shall encourage international and regional intergovernmental organizations and international, regional and national non-governmental organizations to participate 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 participate in the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees shall be in charge of the monitoring of its implementation on the basis of reports provided by States, in particular of the formulation of any opinion or proposal likely to further its effectiveness.

Article 26: 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 out in this Declaration.