Article 5: Purposes

Human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of:

(i) diagnosis and health care, including screening and predictive testing;

(ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as "medical and scientific research";

(iii) forensic medicine and civil, criminal and other legal proceedings, taking into account the provisions of Article 1(c);

(iv) or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and the international law of human rights.

Article 6: Procedures

(a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

(c) When the collection, processing, use and storage of human genetic data, human proteomic data or biological samples are carried out in two or more States, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.

(d) It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a penalty for the person concerned.

Article 7: Non-discrimination and non-stigmatization

(a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.

(b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.

B. COLLECTION

Article 8: Consent

(a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights.

(b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.

(c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

(d) In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when it has important implications for the health of the person and has regard to his or her best interest.

Article 9: Withdrawal of consent

(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.

(b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.

(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.

Article 10: The right to decide whether or not to be informed about research results

When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.

Article 11: Genetic counselling

It is ethically imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate manner. Genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned.

Article 12: Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings

When human genetic data or human proteomic data are collected for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, the collection of biological samples, *in vivo* or post-mortem, should be made only in accordance with domestic law consistent with the international law of human rights.

C. PROCESSING

Article 13: Access

No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security.

Article 14: Privacy and Confidentiality

(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, a family or, where appropriate, a group, in accordance with domestic law consistent with the international law of human rights.

(b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.

(c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.

(d) Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law.

(e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.

Article 15: Accuracy, reliability, quality and security

The persons and entities responsible for the processing of human genetic data, human proteomic data and biological samples should take the necessary measures to ensure the accuracy, reliability, quality and security of these data and the processing of biological samples. They should exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, human proteomic data or biological samples, in view of their ethical, legal and social implications.

D. USE

Article 16: Change of purpose

(a) Human genetic data, human proteomic data and the biological samples collected for one of the purposes set out in Article 5 should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or unless the proposed use, decided by domestic law, corresponds to an important public interest reason and is consistent with the international law of human rights. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) should apply *mutatis mutandis*.

(b) When prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an identifiable person, human genetic data may be used in accordance with domestic law or following the consultation procedures set out in Article 6(b).

Article 17: Stored biological samples

(a) Stored biological samples collected for purposes other than set out in Article 5 may be used to produce human genetic data or human proteomic data with the prior, free, informed and express consent of the person concerned. However, domestic law may provide that if such data have significance for medical and scientific research purposes e.g. epidemiological studies, or public health purposes, they may be used for those purposes, following the consultation procedures set out in Article 6(b).

(b) The provisions of Article 12 should apply *mutatis mutandis* to stored biological samples used to produce human genetic data for forensic medicine.

Article 18: Circulation and international cooperation

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to this data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning human genetic data and human proteomic data and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

(c) Researchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and, subject to the provisions of Article 14, should encourage the free circulation of human genetic data and human proteomic 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. To this end, they should also endeavour to publish in due course the results of their research.

Article 19: Sharing of benefits

(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits 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 new diagnostics, facilities for new treatments or drugs stemming from the research;

(iv) support for health services;

(v) capacity-building facilities for research purposes;

(vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;

(vii) any other form consistent with the principles set out in this Declaration.

(b) Limitations in this respect could be provided by domestic law and international agreements.

E. STORAGE

Article 20: Monitoring and management framework

States may consider establishing a framework for the monitoring and management of human genetic data, human proteomic data and biological samples based on the principles of independence, multidisciplinarity, pluralism and transparency as well as the principles set out in this Declaration. This framework could also deal with the nature and purposes of the storage of these data.

Article 21: Destruction

(a) The provisions of Article 9 apply *mutatis mutandis* in the case of stored human genetic data, human proteomic data and biological samples.

(b) Human genetic data, human proteomic data and the biological samples collected from a suspect in the course of a criminal investigation should be destroyed when they are no longer necessary, unless otherwise provided for by domestic law consistent with the international law of human rights.

(c) Human genetic data, human proteomic data and biological samples should be available for forensic purposes and civil proceedings only for as long as they are necessary for those proceedings, unless otherwise provided for by domestic law consistent with the international law of human rights.

Article 22: Cross-matching

Consent should be essential for the cross-matching of human genetic data, human proteomic data or biological samples stored for diagnostic and health care purposes and for medical and other scientific research purposes, unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights.

F. PROMOTION AND IMPLEMENTATION

Article 23: Implementation

(a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the sphere of education, training and public information.

(b) In the framework of international cooperation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing 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 should be responsible for its monitoring and for the evaluation of its implementation, *inter alia,* on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.

Article 26: Follow-up action by UNESCO

UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of the life sciences and their applications through technologies, based on respect for 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.

（参考３－２）

ヒト遺伝情報に関する国際宣言（仮訳）

総会は、

１９４８年１２月１０日の「世界人権宣言」、１９６６年１２月１６日の二つの国際規約、すなわち「経済的、社会的及び文化的権利に関する国際規約」と「市民的及び政治的権利に関する国際規約」、１９６５年１２月２１日の「あらゆる形態の人種差別の撤廃に関する国際条約」、１９７９年１２月１８日の「女子に対するあらゆる形態の差別の撤廃に関する国際条約」、１９８９年１１月２０日の「児童の権利に関する国際条約」、２００１年７月２６日の「遺伝情報におけるプライバシー保護及び差別禁止に関する国連経済社会理事会決議２００１/３９」、２００３年７月２２日の「遺伝情報におけるプライバシー保護及び差別禁止に関する国連経済社会理事会決議２００３/２３２」、１９５８年６月２５日の「雇用及び職業における差別に関するＩＬＯ条約（第１１１号）」、２００１年１１月２日の「ユネスコ・文化的多様性に関する世界宣言」、１９９５年１月１日に発効の世界貿易機関（ＷＴＯ）を設立する協定に附属する「知的所有権の貿易関連の側面に関する協定（ＴＲＩＰｓ）」、２００１年１１月１４日の「ＴＲＩＰｓと公衆衛生に関するドーハ宣言」並びに国際連合と国際連合の組織である専門機関により採択されたその他の国際人権に関する法的文書を想起し、

１９９７年１１月１１日の総会において、全会一致の賞賛をもって採択され、１９９８年１２日９日の国連総会において支持された「ヒトゲノムと人権に関する世界宣言」、並びに第３０回ユネスコ総会決議２３によって１９９９年１１月１６日に支持された「ヒトゲノムと人権に関する世界宣言の実施のためのガイドライン」をとりわけ想起し、

世界中の幅広い市民の「ヒトゲノムと人権に関する世界宣言」に対する関心、世界宣言が国際社会から受けた確固たる支持、並びに国の法律、規制、規準及び規範や、倫理的な行動規約及びガイドラインについて世界宣言を参考とする加盟国における影響を歓迎し、

医学情報及び個人情報と同様に科学的情報の収集、処理、利用及び保管に関して、人権と基本的自由の保護及び人間の尊厳の尊重に関連する国際的及び地域的な法的文書、並びに国の法律、規制及び倫理的教典文書に留意し、

遺伝情報は、医療情報全般の一部であり、遺伝情報及びプロテオーム情報を含めたすべての医療情報の内容は、前後関係及び特定の状況に大きく依存するものであることを認識し、

ヒト遺伝情報は、個人に関して遺伝的疾病体質を予見することが可能であり、その予見性は、情報を引き出した時点の評価よりも大きくなりえ、世代を超えて子孫を含む家族に対して、事例によっては集団全体に対して、重大な影響を及ぼし、生体試料収集の際にはその意味が必ずしも知られていない情報を含むかもしれず、そして、個人及び集団に対する文化的意義を持ち得ることから、ヒト遺伝情報がその機微な本質により、特別な地位を持つことも認識し、