

Hundred and sixty-sixth Session

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**REPORT ON THE PREPARATION
OF AN INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA**

SUMMARY

In accordance with 165 EX/Decision 3.4.2, the Director-General hereby submits this progress report on the work carried out by UNESCO concerning the elaboration of an international declaration on human genetic data.

Decision proposed: paragraph 39.

INTRODUCTION

1. Pursuant to 165 EX/Decision 3.4.2, the Director-General submits this document which reports on progress towards the elaboration of an international declaration on human genetic data.
2. The document presents, *inter alia*, the work of the ninth session of the International Bioethics Committee (IBC) (Montreal, Canada, 26-28 November 2002) and the fourth session of the IBC Drafting Group (IBC-DRAGR) (Montreal, Canada, 29 November 2002), the main lines of the revised outline of the international declaration on human genetic data (see Annex) and of the international consultation that UNESCO initiated on the Revised Outline.

WORK BY UNESCO SINCE THE 165th SESSION OF THE EXECUTIVE BOARD

Ninth session of the IBC (Montreal, 26-28 November 2002)

3. The ninth session of the IBC, which was held in Canada from 26 to 28 November 2002 at the invitation of this Member State, brought together approximately 250 participants from some 60 countries, including the members of the Committee, the representatives of Member States, representatives of intergovernmental and international non-governmental organizations, and also many eminent figures from scientific, educational and cultural circles.
4. In accordance with the agenda, the IBC examined the draft reports by its two working groups which met in Paris in April 2002, respectively on pre-implantation genetic diagnosis and germ-line interventions (which the IBC prepared at the request of the Intergovernmental Bioethics Committee (IGBC)) and on the possibility of drawing up a universal instrument on bioethics.
5. The ninth session of the IBC was above all an occasion to examine for the first time in public the *outline of the international declaration on human genetic data*, which had been drawn up by the Drafting Group at its first three meetings – in February, April and July 2002.¹ The participants stressed the urgency of defining the internationally recognized principles on the subject. They commended the efforts of the IBC to determine the ethical and legal issues raised by the collection, processing, storage and use of genetic data and agreed that the future instrument on the subject should indeed be a declaration.
6. The discussions focused on several aspects, primarily the need to define genetic data so as to prevent any misinterpretation or misapplication of the future declaration, the issue of the commercialization of genetic data and the sharing of the benefits, which would enable individuals and populations from whom the samples originated to benefit from the research findings obtained thanks to their genetic data. Furthermore, the representatives of vulnerable groups, in particular the disabled, expressed their fear that the use of genetic data might engender new forms of discrimination and stigmatization.

Fourth meeting of the IBC Drafting Group for the elaboration of an international instrument on genetic data (IBC-DRAGR) (Montreal, 29 November 2002)

7. Immediately after the ninth session of the IBC, the IBC Drafting Group held its fourth meeting, which was open to the other members of the IBC present in Montreal.

¹ The corresponding reports are available upon request in English and French from the Division of Ethics of Science and Technology, Bioethics Section.

8. In the course of the meeting, chaired by Judge Patrick Robinson (Jamaica), joint Chairperson of the IBC-DRAGR, the Group took account of the comments and observations that had been made by the observers at the ninth session and embarked on the first revision of the outline's text.

9. The Group considered that a number of themes and ideas that had emerged in the debates in public deserved to be taken more fully into account in the elaboration of the future declaration. The definition and the distinctive features of human genetic data seemed to be a key issue, together with the emphasis that should be placed on them in the constitution of a person's identity. Attention was also drawn to the importance of the distinction between human genetic data collected for research purposes and those collected for clinical diagnosis, for instance as regards consent and genetic counselling.

10. Other issues examined by the Drafting Group with a view to taking them more fully into account in the text were genetic counselling, and the reactions that it produces depending on different social and cultural perceptions, the anonymization of genetic data, with the need to specify the degree of the relationship between the person and the samples, and the question of the sharing of benefits.

Other initiatives

11. It is worth noting that the international scientific community has dealt with the issue of genetic data on many occasions in the recent past and has frequently endorsed the initiative taken by UNESCO to draw up an international declaration on the subject.

12. Thus, at the International Conference on Bioethics in Central and Eastern Europe, organized by the Lithuanian authorities in cooperation with UNESCO (Vilnius, Lithuania, 11-12 November 2002), the participants, in the final declaration adopted on 12 November 2002, underlined "the importance of ensuring the informed consent and the protection of privacy in obtaining and using genetic information" and expressed their support for international efforts towards drawing up an international declaration on human genetic data.

13. Mention may also be made of the Bogotá Declaration, adopted on 10 August 2002 at the second International Congress on the Ethics of Scientific Research, which stipulates in paragraph VII that it is "essential that countries adopt a common international position on the protection of genetic data since they may have implications for a person's innermost concerns". That question was also considered at the second World Conference on Bioethics (Gijón, Spain, 30 September-4 October 2002) and at the sixth World Congress of Bioethics (Brasília, Brazil, 30 October-3 November 2002).

REVISED OUTLINE OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (22 January 2003)

A. The issues

14. The completion of the sequencing of the human genome announced in June 2000 by the Human Genome Project Consortium has opened the way for far-reaching medical research and extensive biomedical applications, particularly with regard to medical diagnosis, prevention, epidemiological research, population genetics studies, etc.

15. Human genetic data – which covers phenotypic and genotypic information obtained from the karyotype and from DNA sequences and their polymorphisms – are of crucial importance to progress in science and medicine. First, the analysis of genetic data contributes to a better

understanding of the evolution of the human genome, particularly as regards its interaction with the environment. Secondly, they can be used in applied biomedical research, for example in the pharmaceutical industry, to reveal any genetic predisposition to react to treatment or to pharmaceutical products. Thirdly, in epidemiological research they can be a useful source of information for public health and social services. Fourthly, they are crucial in individual or family genetic diagnosis, whether in tests to reveal a deleterious genetic mutation or tests to determine susceptibility or genetic predisposition to possible pathologies. Lastly, they are also used for non-medical purposes and have become valuable tools in forensic medicine, for example to identify the bodies of soldiers who have died in action, and in the judicial system, particularly in civil court proceedings, for example to identify a parent, or in criminal proceedings, for example to identify a criminal.

16. While it is important for these practices to continue, it must be noted that they may pave the way to serious misuse – particularly discrimination and stigmatization – which are contrary to human dignity, human rights and fundamental freedoms.

B. Content of the revised outline

17. The drafting of the international instrument on human genetic data is a logical sequel to the *Universal Declaration on the Human Genome and Human Rights* (1997). The future international instrument applies the principles set out in the Universal Declaration to human genetic data; this is an essential field for the respect of human rights, fundamental freedoms and human dignity. Moreover, in its Communiqué adopted on 23 October 2001, the Round Table of Ministers of Science on “Bioethics: International Implications” expressed the view that possible extensions to the Universal Declaration on the Human Genome and Human Rights should be considered.

18. The revised outline of the international declaration on human genetic data (22 January 2003) draws mainly on the IBC reports on “Confidentiality and Genetic Data” (1999) and on “Human Genetic Data: Preliminary Study by the IBC on its Collection, Treatment, Storage and Use” (2002) and is based on the work of the meetings of the IBC Drafting Group (IBC-DRAGR) held between February and November 2002. More generally, the revised outline draws on all the reports drafted by the IBC since 1993. It will be recalled that the IBC dealt with the issue of human genetic data in its reports on “Genetic Screening and Testing” (1994), “Genetic Counselling” (1995), “Bioethics and Human Population Genetics Research” (1995), “Ethics and Neurosciences” (1995) and “Solidarity and International Cooperation between Developed and Developing Countries concerning the Human Genome” (2001).

19. The revised outline is intended to be founded on the fulcrum of universally recognized rights and freedoms, extending the Universal Declaration on the Human Genome and Human Rights and drawing on the existing body of principles and legal standards in the field of bioethics. A number of countries have enacted legislation, taken regulatory measures or adopted ethical standards relating specifically to human genetic data, in some instances, and, more generally, to medical data, personal data and sensitive data.²

20. Furthermore, the revised outline takes account of provisions adopted and reports drawn up by international organizations – in particular the United Nations (UN), the International Labour

² Sensitive data covers information on the ethnic or racial origin of an individual, his or her political opinions, religious, philosophical or other convictions, state of health (physical and mental), sex life, membership of a trade union or association.

Organization (ILO), the World Health Organization (WHO)³ and the United Nations Educational, Scientific and Cultural Organization (UNESCO)⁴ – and regional organizations – such as the Council of Europe,⁵ the Organisation for Economic Cooperation and Development (OECD)⁶ and the European Union.⁷

C. Structure of the revised outline

21. The revised outline is organized on the basis of a statement of principles and standards, which strikes a balance between over-general prescriptions and over-precise ones, which would only be appropriate to an instrument having a binding character (for example, a convention). In fact, the goal of a declaration is to give practical expression to a moral commitment, freely entered into by the community of States; the principles and standards it embodies can then guide the framing of national legislation and regulatory instruments, which can specify and define the prescriptions in detail in accordance with the national legislative framework and legal traditions.

22. In addition, the revised outline of the international declaration makes a clear distinction between the various purposes for which human genetic data are collected and used on the one hand, and, on the other, between the various stages of the collection, processing, storage and use of genetic data despite the redundancy implicit in such distinctions with regard to the drafting of various articles. Therefore, the revised outline respects this economy and follows this logic.

23. The title of the revised outline indicates that the international declaration concerns human genetic data. However, it must be stressed that the international declaration also applies to data that are or could be derived therefrom. This is an important point because various databases, on proteomic data for example, will be rapidly built up in coming years and it would be desirable for the international declaration to anticipate such developments.

24. After the preamble which consists of eight (8) paragraphs, the operative part comprises twenty-seven (27) articles divided into six (6) sections. Following the current practice at UNESCO and other international organizations, each article has a title introducing its subject matter.⁸

25. First of all the preamble refers to the relevant standard-setting texts, particularly the Universal Declaration on the Human Genome and Human Rights, inasmuch as the future international declaration on human genetic data is a logical extension thereof and one of the practical means of implementing the Declaration. It then describes the specificity of human genetic data. Their complexity lies in their dual nature, for they provide both medical and personal information of lifelong relevance and may comprise information on the family, including descendants or, in some

³ See, in particular, the recent report drawn up in 2002 by Mr Dan Brocke and Mrs Chee Heng Leng for the World Health Organization (WHO) and the debate to which it gave rise at the sixth World Congress on Bioethics (Brasilia, Brazil, 30 October-3 November 2002). The report is available in English on the WHO Internet site.

⁴ Specifically, the crossborder flow of personal data was discussed in a book entitled “Privacy and Human Rights”, James Michael, Paris/London: UNESCO/Dartmouth, 1994.

⁵ See, in particular, European Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Convention 108 (1981)) of 28 January 1981 and Recommendation No. R (81)1 on regulations for automated medical data banks, adopted by the Committee of Ministers.

⁶ See, in particular, the Guidelines on the Protection of Privacy and Transborder Flows of Personal Data of 23 September 1980.

⁷ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Council Regulation (EC) No. 322/97 on Community Statistics, concerning access to confidential data for scientific purposes.

⁸ See, for example, the UNESCO Universal Declaration on Cultural Diversity adopted in 2001 by the General Conference of UNESCO.

circumstances, the group to which the individual belongs. Lastly, the preamble highlights the two pivots around which the future international declaration is structured, namely freedom of research and the protection of privacy.

26. Section A contains general provisions which are the keystone of the future international declaration on human genetic data and whose principles apply to human genetic data as a whole, before addressing the various stages of handling such data. It therefore explains key notions, such as human genetic data, the special status of such data or a person's identity and reaffirms the principle of non-discrimination and non-stigmatization. It also states the purposes for which and the procedures by means of which human genetic data may be handled, stressing in particular the need for transparent procedures providing for the informed participation of society.

27. Section B deals with the collection of samples that will be used to produce human genetic data. Human genetic data may be produced from cell (blood or other) or tissue samples taken from a person through invasive (a blood sample, for example) or non-invasive (strand of hair with the hair bulb) procedures. The revised outline considers that the person must give prior, free, informed and express consent for the collection of genetic data in all these cases. In connection with consent, this section of the revised outline also deals with the possible withdrawal of consent, which arises in medical research (for example, voluntary population screening) or scientific research (for example, voluntary participation in a research project). It takes up the principle of the right to decide not to be informed, which is already affirmed in the *Universal Declaration on the Human Genome and Human Rights*,⁹ and stipulates that genetic counselling must be offered, without obligation, when human genetic data are collected for the purpose of health care.

28. Section C raises the issues of access, quality and security, which are core concerns in the processing of human genetic data. It affirms the right of each person to have access at all times to his or her genetic data and specifically addresses the question of the confidentiality of genetic data associated with an identifiable person, family or group, thus extending the provision of Article 7 of the *Universal Declaration on the Human Genome and Human Rights*.¹⁰ It also deals with the issue of anonymization and lays emphasis on the precautions that must be taken if the person's identity can be re-established. Lastly, reference is also made to the responsibility of the professional bodies concerned and the bodies responsible for the processing of genetic data to ensure the accuracy, reliability, quality and security of such data.

29. The sharing of scientific knowledge and fair access to human genetic data are at the heart of Section D, which deals with the many uses of human genetic data for medical and non-medical purposes. It encourages the free circulation of human genetic data among researchers, while calling for the crossborder flow of such data to be regulated. Lastly, the section addresses the issue of sharing the benefits resulting from the use of human genetic data collected for medical and scientific research and indicates the possible conditions relating to such sharing.

30. The storage of human genetic data is the subject of Section E. While such storage might for the time being seem to pose no acute problems in many countries of the world, their rapid accumulation and numerous possible uses will make the question of storage particularly difficult. For that reason, the revised outline sets out the principles that must underlie the management of such data at the national level and affirms the duty of countries to establish a monitoring and management system based on the principles of independence, multidisciplinary, pluralism and

⁹ Article 5(c) "The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected".

¹⁰ Article 7 "Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law".

transparency. The section also deals with the destruction of human genetic data and draws a distinction between those collected in the course of a criminal investigation and those collected as part of civil proceedings. Lastly, it deals with cross-linking of human genetic data, stipulating that such cross-linking shall not be authorized unless the data have been collected for the same purpose.

31. Lastly, Section F deals with the promotion and implementation of the international declaration on human genetic data. It recalls the duty of States to give effect to the principles set forth in the declaration through legislative measures and regulations and by action in the sphere of education, training and information. In many areas, experience proves that laws or regulations are effectively applied only when they are supported by action in those spheres. Lastly, the revised outline proposes that UNESCO's International Bioethics Committee (IBC) and Intergovernmental Bioethics Committee (IGBC) be responsible for the dissemination of the principles set forth in the international declaration and for its implementation.

D. International consultation on the revised outline

32. In accordance with 165 EX/Decision 3.4.2, a broad international written consultation on the *revised outline of an international declaration on human genetic data* (22 January 2003) was launched by UNESCO in February 2003.

33. A questionnaire was prepared – in English, French and Spanish – in order to gather any comments or suggestions concerning the revised outline. The questionnaire, together with a brief summary of the outline, was sent to all Member States and Associate Members, to international organizations (the United Nations and its specialized agencies, as well as over 100 intergovernmental and non-governmental organizations) and relevant national bodies (national ethics committees, commissions for the protection of privacy, universities, UNESCO Bioethics Chairs, etc.), and to some 150 specialists and personalities, including former members of the IBC. A number of representatives from the private sector, particularly the pharmaceutical industry, were also invited to take part in the international written consultation. All the documents concerning the consultation, together with the revised outline, are available on request from the Bioethics Section of the Division of Ethics of Science and Technology, as well as on the Internet (www.unesco.org/ibc).

34. Conscious of the importance of associating the main stakeholders with the drafting of the future declaration, the IBC furthermore decided to organize, on the occasion of the fifth meeting of the Drafting Group, a **Public Hearings Day** on human genetic data and the revised outline, which took place on 28 February in the Principality of Monaco. This Day brought together various groups particularly concerned by the proposed declaration (ten associations and institutions representing indigenous people, women, children, the disabled, patients, doctors and researchers, together with the private sector and insurance companies) (166 EX/11 Add.).

35. Finally, it should be noted that the Director-General also wished to include the question of genetic data in the agenda of the first meeting of the Inter-Agency Committee on Bioethics, which took place on 14 and 15 March 2003 at UNESCO Headquarters in Paris. The revised outline was thus brought to the attention of this Committee, composed mainly of United Nations institutions but also open to other intergovernmental organizations engaged in activities relating to bioethics.

CONCLUSIONS

36. The *Revised Outline of the International Declaration on Human Genetic Data* (22 January 2003), annexed to this report, is the outcome of the preliminary study carried out by the IBC at its

ninth session (Montreal, 26-28 November 2002) and the discussions at the fourth meeting of the IBC Drafting Group (Montreal, 29 November 2002).

37. This revised outline is provisional in character. In its present form, it continues to be the subject of consultations within the international community, as mentioned in paragraphs 33 to 36 above. The text will be progressively refined to take account of any relevant comments, corrections and suggestions, with a view to its adoption at the 32nd session of the General Conference following its possible submission to the 167th session of the Executive Board.

38. An overview and analysis of the replies received at the conclusion of the international consultation will be submitted in particular to the tenth session of the IBC (Paris, UNESCO Headquarters, 12-14 May 2003). It will also be brought to the attention of the third session of the Intergovernmental Bioethics Committee (IGBC) (Paris, UNESCO Headquarters, 23-24 June 2003) and the meeting of government experts responsible for finalizing the draft international declaration (Paris, UNESCO House, 25-27 June 2003), with a view to its adoption by the General Conference in October 2003.

39. The Executive Board, after examining this report and having regard to the foregoing observations, may wish to adopt a decision along the following lines:

The Executive Board,

1. Having examined document 166 EX/11 and Annex, and document 166 EX/11 Add.,
2. Congratulates the International Bioethics Committee (IBC) and particularly its Drafting Group for the quality of the work carried out;
3. Takes note of the initiatives taken by the Director-General to associate Member States, intergovernmental and international non-governmental organizations, and relevant national bodies with the drafting of the international declaration on human genetic data;
4. Invites the Director-General to submit a consolidated text, taking account of the results of the international consultation, to the meeting of government experts (category 2) responsible for finalizing the draft international declaration on human genetic data (Paris 25-27 June 2003), with a view to its adoption by the General Conference at its 32nd session.

ANNEX

**REVISED OUTLINE OF THE INTERNATIONAL DECLARATION
ON HUMAN GENETIC DATA**

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 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, 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 the 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 constitute a special category of information because they provide scientific, medical and personal information, and they 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 the 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 genetics 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-stigmatization

- (a) Human genetic data shall not be used for discriminatory purposes nor in a way that may lead to the stigmatization 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 legislation 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 the person concerned 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, they may be used for those purposes, in accordance with the provisions under Article 5(b), even in the absence of consent of the person concerned. 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 such 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 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 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 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 such 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 judgement 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.

Hundred and sixty-sixth Session

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**REPORT ON THE PREPARATION OF AN INTERNATIONAL
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**REPORT ON THE PUBLIC HEARINGS DAY ON HUMAN GENETIC DATA
AND THE FIFTH MEETING OF THE DRAFTING GROUP
OF THE INTERNATIONAL BIOETHICS COMMITTEE**

(Monaco, 28 February and 1-2 March 2003)

ADDENDUM

SUMMARY

The present report, an addendum to the report of the Director-General (166 EX/11) on the preparation of an international declaration on human genetic data, contains a report on the Public Hearings Day on human genetic data (Monaco, 28 February 2003) and on the work carried out by the Drafting Group of the International Bioethics Committee (IBC) at its fifth meeting held in Monaco on 1 and 2 March 2003.

I. INTRODUCTION

1. At the kind invitation of the Principality of Monaco, the fifth meeting of the Drafting Group of the International Bioethics Committee (IBC) was held in Monaco from 28 February to 2 March 2003.

2. The International Bioethics Committee, aware of the importance of involving the principal actors in the preparation of the future international declaration on human genetic data, decided on that occasion to organize a **Public Hearings Day** on human genetic data and the revised outline of the declaration, which was held on 28 February.

Public Hearings Day on human genetic data

3. The Public Hearings Day, which was opened in the presence of Mr Philippe Deslandes, Minister of the Interior of the Principality of Monaco, Ms Michèle Jean, Chairperson of IBC, and Mr Pierre Sané, representing the Director-General, brought together some 50 participants, including the members of the IBC Drafting Group, the principal speakers and approximately 30 observers – representatives of intergovernmental and non-governmental organizations and experts.

4. Chaired by Ms Nicole Questiaux, Co-Chairperson of the IBC Drafting Group, the Public Hearings Day provided an opportunity for representatives of groups and categories of individuals particularly affected by the new declaration to debate the ethical questions raised by human genetic data. In all, representatives of nine principal groups were invited to take the floor: international bodies serving as forums of reflection on bioethics (International Society of Bioethics (SIBI)), doctors (World Medical Association (WMA)), clinicians (European Forum for Good Clinical Practice), children (World Association of Children's Friends (AMADE)), women (International Federation of University Women (IFUW)), the disabled (Inclusion International), researchers (in particular from developing countries), the insurance industry (French Federation of Insurance Companies) and the pharmaceutical industry (EuropaBio). Each speaker presented the position of their organization or institution with regard to human genetic data and made specific comments on the revised outline of the declaration.

5. The discussions gave rise to a fruitful exchange of views among the speakers, the observers and the Drafting Group. First of all, the form of the instrument – a declaration – met with unanimous approval. A similar consensus emerged with regard to the structure of the text, which establishes a clear distinction, on the one hand, between the different purposes for which human genetic data are collected and used and, on the other, between the different phases of dealing with such data, namely collection, processing, use and storage, despite the inevitable overlap arising from such distinctions in the wording of the various articles.

6. Secondly, attention was drawn to the difficulty of defining human genetic data and clarifying its special status, although this was seen as something which had to be overcome. While the title of the revised outline indicates that it concerns human genetic data, the international declaration also applies to data and information which are or may be derived from such data and to biological samples used to produce such data.

7. Thirdly, the debate focused on the declaration's wording and terminology, which need to be clarified. For example, the list of the different purposes for which human genetic data may be collected, processed, used or stored was regarded as too restrictive in the light of current research. Anthropological research, for instance, should be included. Lastly, bearing in mind Article 4 of the Universal Declaration on the Human Genome and Human Rights which stipulates that "The human genome in its natural state shall not give rise to financial gains", and in line with the report of the

International Bioethics Committee on “Ethics, intellectual property and genomics” (2001), the future declaration must make reference to the question of the ownership regime or other arrangement which would be applicable to human genetic data, even though it is up to the Member States to define the limits and scope of such a regime.

8. The Public Hearings Day provided an additional opportunity to ensure the transparency of the work of IBC and to gather valuable observations for use in finalizing the revised outline of the international declaration on human genetic data.

Fifth meeting of the IBC Drafting Group

9. The Drafting Group met on the two days following the Public Hearings Day to undertake its first re-examination of the revised outline on the basis of the comments and observations made during the hearings. The Drafting Group focused particular attention on the questions of the definition of human genetic data, the distinction between data, information and samples, and their special nature. To avoid confusion, it was considered important to revise the outline to include, where necessary, reference to the biological samples used to produce human genetic data. The special status of such data is determined by three factors: the data have predictive ability of lifelong relevance; they have an impact not only on the persons concerned but also on their families, extending over generations, and, in some instances, on the group to which the person belongs; they contain potential information which cannot be known at the time of collection.

10. The Drafting Group made other modifications to the articles, notably with a view to incorporating in the text a reference to the rights of children and women, explaining more precisely the purposes for which the data are collected and used, and clarifying the concepts of consent and ownership.

11. Lastly, the Drafting Group entrusted its co-chairpersons, Ms Nicole Questiaux and Mr Patrick Robinson, the Chairperson of IBC, the Rapporteur of the Drafting Group, Mr Georges B. Kutukdjian, and the Secretariat with the task of undertaking a preliminary analysis of the replies received in response to the written consultation with a view to the finalization of a new version of the declaration, which will be examined by the International Bioethics Committee at its tenth session, to be held in Paris from 12 to 14 May 2003.