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# **REPORT ON CONFIDENTIALITY AND GENETIC DATA**

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**WORKING GROUP OF THE IBC  
ON CONFIDENTIALITY AND GENETIC DATA**

Division of the Ethics  
of Science and Technology

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## I. INTRODUCTION

1. The Universal Declaration on the Human Genome and Human Rights (hereinafter called the Declaration), adopted by the General Conference of UNESCO on 11 November 1997, states in 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”*.

2. This provision has arisen out of an imperative need. Indeed, the development of science is now such that it is the cause of some concern. The international community can not allow human beings to undergo operations and be subjected to research without raising barriers to safeguard their dignity.

3. The Declaration seeks to ensure the development of human genetics in a way that fully respects the dignity and rights of the human person and is beneficial to humanity as a whole. Respect for the dignity and fundamental rights of the human person is a major ethical imperative and is affirmed in Article 2 of the Declaration:

*“a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.*

*b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity”*.

4. In a field as specific as human genetics, the Declaration states in Article 1 that the human genome is *“in a symbolic sense, ... the heritage of humanity”*.

5. The totality of an individual’s genetic data constitutes his genome. It belongs to him personally and, at the same time, forms part of the *“fundamental unity of all members of the human family”* (Art. 1).

6. Although this second aspect of the genome is an important point of the Declaration, it must be stressed that the essential aim of this Declaration is to safeguard the dignity of the human person.

7. In the context of genetic research and its applications, the principle of respect for dignity implies that human beings must be recognized as such and not be considered by science as objects.

8. Respect for human dignity must consider not just one of the constituent parts of an individual but his “entire being” in its fullness.

9. The basis for the principle of confidentiality of genetic data is the human right to privacy, which has been recognized in the major human rights instruments adopted after the Second World War, starting with the Universal Declaration of Human Rights.

10. Article 12 of the Universal Declaration of Human Rights of 1948 provides: *“No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks”*.

11. Article V of the American Declaration of the Rights and Duties of Man of 1948 (in point of time, actually this Declaration was adopted before the Universal Declaration of Human Rights) provides: *“Every person has the right to the protection of the law against abusive attacks upon his honour, his reputation, and his private and family life”*.

12. Article II of the American Convention on Human Rights of 1969 provides: *“(1) Everyone has the right to have his honour respected and his dignity recognized. (2) No one may be the object of arbitrary or abusive interference with his private life,*

*his family, his home, or his correspondence, or of unlawful attacks on his honour or reputation. (3) Everyone has the right to the protection of the law against such interference and attacks”.*

13. Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 provides: *“(1) Everyone has the right to respect for his private and family life, his home and his correspondence. (2) There shall be no interference by a public authority with the exercise of this right except such as in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health and morals, or for the protection of the rights and freedoms of others”.*

14. Article 17 of the International Covenant on Civil Political Rights (ICCPR) of 1966 provides: *“(1) No one should be subjected to arbitrary or unlawful interference with his privacy, family, honour or correspondence, nor to unlawful attacks on his honour and reputation. (2) Everyone has the right to the protection of the law against such interference or attacks”.*

15. Finally, in dealing with the issue of confidentiality, Article 10 of the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention of Human Rights and Biomedicine of 1997 provides: *“(1) Everyone has the right to respect for private life in relation to information about his health. (2) Everyone is entitled to know any information collected about his health. However, the wishes of individuals not to be so informed shall be observed. (3) In exceptional circumstances, restriction may be placed by law on the exercise of the rights, contained in paragraph 2 in the interest of the patient”.*

16. In order to ensure respect for the dignity of the human person, the Universal Declaration on the Human Genome and Human Rights solemnly proclaims the confidentiality of genetic data. This confidentiality, thus affirmed, seeks to protect the individual against the disclosure of the data that belongs to him.

17. However, while the principle of confidentiality is recognised, its protection must necessarily be regulated. The implementation of the protection of the human genome, which is so closely linked to the human person, must be supported by the executive, legislative and judicial powers. Indeed, the intervention of the legislative branch, which expresses the opinion of the majority in a democracy, is an additional guarantee for the protection of human rights. Furthermore, in order to support the need for protection by law, the provisions of Article 7 are accompanied by those of Article 9 which sets forth the objectives that the law must bear in mind in the event of limitations on the principle of confidentiality.

18. What would be the effectiveness of a protection whose object is unknown to its beneficiaries? This is why, over and above the principle of confidentiality as proclaimed, and in order that this principle may not remain a pious wish, Articles 17, 18 and 19 of the Declaration invite States to solidarity with respect to individuals and amongst them.

## **II. IDENTIFICATION OF THE DIFFERENT KINDS OF GENETIC DATA**

19. The human genome is composed of about 100,000 or more genes and 3 billion basepairs of DNA. Although the overall organization of DNA and great majority of genes are common to all human beings, there occur a large number of structural differences between individuals. Some of these differences, alone or combined, are unique to each individual, which can be considered as “private information” for a

given individual or family. Some other changes are shared by all individuals belonging to a lineage or an ethnic group.

20. The genetic data which can be considered as subject to confidentiality are any genetic data which enters into one of these categories (data specific for an individual or a group of individuals). Genetic information about people comes in many forms. For example, a person's blood type (A, B, AB, O), the colour of a person's hair and many features of appearance. At another level, there is information in the form of karyotype, i.e. chromosome composition: the sex chromosomes X and Y, and various unusual compositions such as the number of X and/or Y chromosomes, or the number of copies of chromosome number 21 are some examples.

21. In recent years, there has been an explosion in the sophistication of genetic information that can be gleaned about an individual, and from samples of that individual: tissue, blood, urine or even sweat. These derive from examination of the individual's DNA and can be obtained by a number of strategies. For example, they could come in the form of the size specific restriction fragments (the piece of DNA that encodes a particular sequence residing between two adjacent sites that are cut by a particular DNA cutting enzyme that recognised a particular DNA sequence as a cut site). Probes that recognise specific DNA sequences are then used in the analysis of sizes of the DNA produced by various DNA cutting enzymes (restriction enzymes). More recently, *in vitro* enzymatically synthesized DNA, using short specific DNA primers to direct which sequences are synthesized, have been introduced for some kinds of analysis of both DNA and RNA. For even greater specificity, specific DNA sequences can be sequenced and the arrangement of basepairs determined.

22. Genetic information in these various categories is obtained for different reasons. For example, karyotyping is often carried out for purposes of prenatal diagnosis for the identification of an extra copy of chromosome 21, indicating a prenatal genetic disorder and often resulting in termination of pregnancy. This procedure also reveals the gender of the foetus, sometimes revealed to the parents, sometimes not. In addition, the procedure also detects abnormalities in the number of X or Y chromosomes, an anomaly not frequently revealed to the parents.

23. The DNA "fingerprints" are being widely used for identifying individuals and the relatedness of individuals. Both military and police organizations are accumulating banks of DNA from individuals for forensic and other identification purposes. Immigration services and courts are using such identification to characterize the relatedness of individuals and paternity.

24. Information derived in the form of DNA sequence has been derived from the international sequencing efforts of the Human Genome Project where the full sequencing of the human genome is expected to be completed in the near future.

25. Specific portions of the sequencing effort have been delineated for the identification of diseases that are the consequence of DNA sequence alterations transmitted in the human germ line.

26. Much of the currently generated individual genetic data are derived from medical studies whose purpose is to identify a specific DNA sequence for genetically determined diseases. Some other genetic data (DNA fingerprints) are generated for forensic studies aiming to identify a suspected person or to identify a biological relationship between individuals or between parents and children. A third category of data are generated for population genetics studies to establish, for example, genetic relations between different ethnic groups. Genetic data generated for medical reasons are often used to confirm a clinical diagnosis of a disease. However, with the introduction of tests for "genetic risks", some medical data can serve to predict the likelihood of an individual to develop a disease, even if the clinical signs of the disease are not apparent at the time of data collection.

27. The misuse of this type of genetic data generated for medical reasons may lead to individual discrimination based on genetic background. Genetic data generated for non-medical reasons is not usually used to determine information related to a disease or a genetic risk for a disease. However, such data also should be carefully examined against possible misuse for discrimination of individuals for familial or ethnic reasons.

#### Genetic data generated for medical purposes

28. Some human diseases are known to be caused by an inherited germ-line mutation. It has now become possible to identify disease causing germ-line mutations for a large number of diseases both prenatally and postnatally. In some countries, molecular diagnosis has become common in the medical community. Mutation analysis has also been used to analyse healthy relatives of persons affected with a genetic disease.

#### Genetic data generated for non-medical reasons

29. This type of genetic data is generated mostly for forensic studies to identify a person through DNA fingerprints. Judiciary systems in most countries are equipped with material for DNA fingerprinting which is used to compare, for example, the DNA fingerprints of a suspected individual with that biological material (blood, semen,...) collected at the scene of a crime. DNA fingerprinting is also used for identification of the biological father of a child, most often to resolve disputes over an inheritance.

30. Genetic data is also collected for DNA fingerprinting in the army, as well as for some immigration requests to establish, for example, a genetic relationship between different members of a kindred.

31. Although there are no examples for the time being, DNA fingerprints may serve to identify the origin of an individual, or a group of individuals. The history of humanity has tragic examples of religious or ethnic discriminations based on, for example, skin colour or skull dimensions. There is a risk of using the DNA profiles of individuals for similar kinds of discrimination<sup>(1)</sup>.

### **III. THE PRINCIPLE OF CONFIDENTIALITY AND GENETIC DATA**

32. The confidentiality of data stemming from scientific research has been emphasised in a number of international documents such as the Nuremberg Code, the Helsinki Declaration (the World Medical Association, WMA) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences, CIOMS). Furthermore, legal instruments have been adopted in order to protect the confidentiality of personal or sensitive data<sup>(2)</sup>, not to mention national legislations protecting the right to privacy<sup>(3)</sup>.

33. Although genetic data may be characterized as medical and personal data, and, therefore, subject to the legal regime that would ordinarily apply to such data, a special regime for genetic data is warranted because it provides sensitive information not only about an individual, but also about his family (relatives and descendants). Hence this information is of a transgenerational nature. Genetic data, therefore, has characteristics that are at the same time individual and shared; for both reasons, the regime of

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1. See the Report of the IBC on Bioethics and Human Population Genetic Research (*Proceedings of the Third Session of the IBC*, Vol. I, 1995).

2. By the United Nations Commission on Human Rights, the Council of Europe, the Organization for Economic Development and Cooperation (OECD) and the European Commission.

3. See Michael, J. *Privacy and Human Rights*. Paris: UNESCO & Dartmouth, 1994.

confidentiality and access to information needs to be carefully elaborated to guard against misuse of the data that can be damaging to an individual and his family.

### **Features of the Principle**

34. As set out in Article 7 of the Declaration, there are two conditions for the application of the principle of the confidentiality of genetic data.

35. First, the data must be “*associated with an identifiable person*”. If the data is anonymized, that is, is not related to an identifiable person, the requirement for confidentiality does not apply. This is reasonable and logical, since the principle of confidentiality attaches to a person: if there is no identifiable person with whom the data can be associated, there is no need for confidentiality. It is not enough that the data can be associated with any human being: for the principle of confidentiality to apply, the data must be associated with an identifiable person, i.e. a person whose identity can be established. This limitation on the principle of confidentiality is essential to allow certain legitimate uses of genetic data, for example for research or epidemiological purposes. In these cases, the coding of genetic data should ensure anonymity of information and the coding system should be strictly confidential.

36. The phrase “*and stored or processed for the purpose of research or any other purpose*” describes genetic data which requires confidentiality; that is, data is stored or processed for research or any other purpose, including diagnosis and treatment. Indeed, the storing and computerised processing of genetic data in general, as well as collections of DNA samples over many years, raise specific issues as to the confidentiality of the data concerned. For example, the issues concerning the repository of this data, the authority holding the coding system of its anonymity and the authority responsible for its possible uses, will have to be addressed in each country within its legal framework. Furthermore, attention should be paid to the constitution, exchange and transfer, and use by the private sector of genetic data banks without breach of confidentiality.

37. The second condition for the application of the principle is that data which satisfies the test of association with an identifiable individual “*must be held confidential in the conditions set by law*”. This condition anticipates the regime for disclosure.

### **Disclosure**

38. Disclosure of genetic data implies free, informed and explicit consent. This consent can only be given to a medical unit which is bound by medical secrecy.

39. Disclosure of genetic data – justifiable only in exceptional situations foreseen by law – must always be preceded by a case-by-case analysis of harms and benefits with the idea of minimising harms and maximising benefits.

40. Several considerations could permit disclosure of genetic data, for example, to the person concerned, family members, third parties and for research purposes<sup>(4)</sup>.

#### **A. Person Concerned**

41. Article 5(c) of the Declaration provides that “*the right of an individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected*”. This is a special provision, particularly relevant to predictive genetic tests, that entitles the person tested to be informed of the

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4. For an analysis of this issue, see study entitled “*Privacy, Confidentiality and Genetic Information*” by Bartha Maria Knoppers, prepared for the IBC. This study is available, in English and French, at the Division of the Ethics of Science and Technology of UNESCO.

results of genetic examination<sup>(5)</sup>. In a normal situation it would not be reasonable to withhold such results from the person concerned.

42. Are there situations in which the results of genetic examination may be withheld from the person tested against that person's wishes? Where the information is sensitive and could be psychologically damaging to the person tested, the question may arise whether it should be withheld or whether its transmission should be delayed (the latter is so called "therapeutic privilege" of delayed disclosure). In the absence of a provision allowing for derogation from Article 5(c), for example, in the interest of the patient, it would seem that the person tested could insist on the information being given to him/her.

43. Note that the European Convention on Human Rights and Biomedicine provides in Article 10(3) for a special exception to the right (in its second paragraph) whether to be informed or not of information about one's health: "*in exceptional cases, restrictions may be placed on the exercise of the rights contained in paragraph 2 in the interest of the patient*"<sup>(6)</sup>. There is thus in this Convention, unlike the Declaration, a particular provision that would allow for the withholding of information where it is felt that such information would be psychologically damaging to the person tested<sup>(7)</sup>.

44. Article 5(c) of the Declaration also gives the person tested the right not to be informed of the results of genetic examination. There might be a situation in which it is felt that the person tested should, against his wishes, be informed - perhaps a rarer situation than the one in which it is felt that the person tested should not, against his wishes, be informed. In the case of a person having expressed a wish not to be informed of the results of genetic research, how can this right be reconciled with the necessity of informing him of danger, if such research should reveal a deleterious mutation or a genetic susceptibility to an illness that could be prevented for the person concerned or members of his/her family?

45. In the absence of a provision allowing for derogation from Article 5(c), for example, in the interest of family members or the general public, the person tested could insist on the information not being given to him/her.

46. This right not to know applies above all in the identification of a genetic predisposition to genetic disorders for which no treatment or prevention is available. The question is whether a doctor ought to inform a patient about a genetic condition that will not reveal itself for many years and for which there is no treatment. Given the present state of our knowledge of human genetics, a number of doctors and geneticists agree that this is inappropriate.

## B. Family Members

47. There could be imperative reasons that genetic information, while of an individual character, be shared among family members. The explicit, informed consent to disclosure of the person tested is required. The compelling social considerations that could justify disclosure to family members include public health and the protection of the rights and freedoms of others. Family members whose health and general welfare

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5. See the Report of the IBC on Genetic Counselling (*Proceedings of the Third Session of the IBC*, Vol. I. UNESCO, 1995), which has emphasized the need for non-directive genetic counselling.

6. For a consideration of this issue, see Knoppers, *supra* note 4, at page 3, and the *1995 WHO Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetic Services* – par. 7.2.1, pp. 38-39.

7. That Convention also has a general exception provision in Article 26. But that would not apply to the right whether to be informed in Article 10(2). However, it would apply to the broader right of a person in Article 10(1) to "respect for private life in relation to information about his or her health".

could be affected by the genetic data of an individual, could be informed of as much of that data as is relevant to them. Such information should exclude aspects of the data that are specific to the individual and have no implications for family members.

48. Ethical obligations to vulnerable persons of limited competence and/or decision-making capacity may require a special approach to protect their interests. For example, in exceptional cases when an individual (a patient) is functionally unable to understand a genetic risk, only those legally responsible for that individual may be involved and genetic counselling may be offered. Assignment of the (voluntary) decision to a team of experts may be accepted as a last resort because of limited means of understanding and assimilating information by a counsellee.

49. In the particular case of monozygotic twins (where genetic testing of one individual reveals the status of the other), if one twin wishes to be tested and the other does not, a physician may decide (after counselling) to test the twin who requests it.

50. Disclosure of information (of genetic risk, positive results of a presymptomatic test) to a spouse or partner could only be envisaged in cases where the genetic condition of one spouse/partner may affect the other spouse's/partner's future even when children are not intended. That disclosure should be via the patient him/herself and with his/her explicit consent.

51. The special aspects of certain types of genetic diagnosis proposed during prenatal life and infancy must also be taken into consideration. Parents have the right to know about the state of a child's health, whether the illness be curable or not. The family of the child, whether unborn or born, has the special responsibility of ensuring that genetic data remains confidential: parents remain the guardians, on behalf of their children, of information about them. It is their duty, if necessary in agreement with genetic counsellors and pediatricians, to decide to what extent, when and in what form the child be informed about his/her genetic data. However, they should be particularly vigilant, considering the vulnerability of children and the lifetime consequences of disclosure of their genetic data.

### C. Third Parties (Insurers/Employers/Schools/Adoption Agencies)

52. The question of disclosure of genetic data to third parties such as insurers and employers raises serious ethical objections. It is argued that the human right to work<sup>(8)</sup> and the human right to social insurance<sup>(9)</sup> (at least, health insurance as distinct from life insurance) warrant prohibiting the disclosure of genetic data to employers and insurers, even if the concerned individual has consented<sup>(10)</sup>. The Working Group believes that consent given out of fear of not being employed or insured has not been freely given.

53. Moreover, it should be kept in mind that a genetic test may be performed for preventive diagnostic purposes. Hence, the data derived from that test does not necessarily imply that the individual is at a particular risk provided that preventives measures are taken. Moreover, such disclosure may expose kin of an individual, since genetic material is shared by biological relatives. Hence, identifying a genetic causative agent in one person has implications that go beyond that person and insurers and employers may, beyond a given individual, hold information about that individual's relatives.

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8. See Article 23 of the Universal Declaration of Human Rights and Article 6 of the International Covenant on Economic, Social and Cultural Rights.

9. See Article 22 of the Universal Declaration of Human Rights and Article 9 of the International Covenant on Economic, Social and Cultural Rights.

10. 1995 WHO Guidelines, *supra* note, par. 7.2.6, p. 45.

54. Employers and insurers who deny employment and insurance on the ground of an individual's genotype are at variance with Article 6 of the Declaration which stipulates that "*no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity*".

55. An alternative approach is to allow access to the information but to prevent it from being used for discriminatory purposes<sup>(11)</sup>. It is difficult to identify the compelling social interest that is served by disclosure of genetic data to employers and insurers.

56. The fundamental issue raised by these two approaches, particularly in relation to insurance, is the relationship between an individual's freedom to contract, on the one hand, and Articles 7 and 9 on the other. Does the principle of confidentiality of genetic data override an individual's freedom to contract with an insurer on the basis of data that he/she wishes to disclose to that insurer? That question is not fully answered by the Declaration.

57. Nevertheless, genetic data could be disclosed if a job involves responsibility for another's life or safety, when a worker's genetic disorder (particularly some late onset neurological conditions) may seriously endanger another individual. In certain instances, an applicant's genetic condition might make him/her especially vulnerable to specific environmental/occupational substances and therefore an employer might want to have access to the results of a specific genetic test<sup>(12)</sup>. An employer may request testing as a condition of continued employment in cases where an employee has a family history which indicates a significantly elevated risk for a disorder which may involve a risk to other persons.

58. As far as access to education is concerned, disclosure of genetic data to schools may only be justified for compelling reasons in the interests of a child. This disclosure should be made to the medical unit; the explicit, informed consent (to disclosure) of the parents of the child, or those legally responsible for him/her, is required, as well as commitment by the unit that the data will not be used for discriminatory purposes.

59. Similarly, although adoption agencies may have a legitimate interest in an individual's genetic data, any provision to allow access to such data should seek to ensure that the data is not used for discriminatory purposes.

60. Disclosure of a child's genetic background to adoptive parents is justified when the child is at risk for a serious disorder that generally manifests itself in childhood or adolescence (there is no need for disclosing increased risk of late onset disorders) or a family history indicates significantly elevated risk of a psychiatric disorder with which the adoptive parents may be unable to cope.

61. Disclosure of genetic data about biological parents to the adoptive parents (without person identification) is justified when genetic information is relevant to the child's genetic condition. Genetic data about biological parents may be disclosed to the adopted individual when he/she reaches adulthood (without person identification of biological parents).

#### D. Research and Epidemiology

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11. *Ibid.*

12 See the Report of the IBC on Genetic Screening and Testing (*Proceedings of the Second Session of the IBC*, Vol. I. UNESCO, 1995).

62. In its Article 10, the Declaration provides that research on the human genome should not “*prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people*”.

63. For research purposes, disclosure should be with consent, or anonymized data only should be used.

64. Disclosure of genetic data for research can be warranted for scientific and public interest and public health purposes. Obviously, any provision for derogation from the principle of confidentiality for research must take account of the need not to identify individuals; that can be done by, *inter alia*, anonymizing genetic data.

65. In particular, the results of genetic population surveys should not be used in a way that might stigmatise the groups of populations concerned, let alone lead to situations of discrimination of individuals belonging to these groups. This implies that individual researchers and research institutions should be particularly alert to this risk and exercise responsibility in disclosing such results.

66. If biological samples used for research are identifiable as belonging to particular individuals, disclosure may be justified when a researcher comes across a person with a monogenic genetic disorder which can be effectively treated (effective therapy available) or finds a genetic feature – such as familial chromosomal structural rearrangement – which involves increased risk of having affected children. Preventive measures in such cases are available and may be offered. Informed consent given prior to research must include the conditions under which the data might, if need be, be disclosed.

#### **IV. LIMITATIONS ON THE PRINCIPLE OF CONFIDENTIALITY**

67. Derived as it is from the right to privacy enshrined in a number of international instruments, the principle of confidentiality has the kind of limitations, explicit or implied, that are attached to that right in those instruments<sup>(13)</sup>. The limitations are set out in Article 9 of the Declaration as follows:

*“In order to protect human rights and fundamental freedoms, limitations to the principle of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights”.*

68. Any law should be drafted in accordance with the international law of human rights. The limitations set out in this Article relate not only to the principle of confidentiality (Art. 7), but also to the principle of consent by an individual as a requirement for research, treatment or diagnosis affecting that individual’s genome

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13. Broadly speaking, these may be described as public interest exceptions or derogations. Article 8(2) of the European Convention for the Protection of Human Rights and Fundamental Freedoms provides: “There should be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interest of national security, public safety or the economic well being of the country, for the protection of health or morale, or for the protection of the rights and freedoms of others”.

The European Convention on Human Rights and Biomedicine, in its Article 10(3), provides: “In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interest of the patient”; Article 26 provides: “(1) No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others”.

(Art. 5). Although the two principles are not unrelated, the Working Group's focus is on the principle of confidentiality.

### **Conditions for the Application of Article 9 of the Declaration**

69. Article 9 identifies three sets of circumstances in which limitations may be placed on the principle of confidentiality.

70. First, since the basic norm is the primacy of the principle of confidentiality, the article stresses the exceptional nature of limitations on that principle, which are given a very narrow and confining scope "*in order to protect human rights and fundamental freedoms*". The principle of confidentiality is an offshoot of the human right to privacy; as such, derogations from that principle must be strictly confined to certain defined areas.

71. Second, the intentionally narrow ambit of the limitations is emphasized by the requirement that limitations "*may only be prescribed by law*". This is consistent with the approach in the ICCPR<sup>(14)</sup>. The requirement ensures that any limitations placed on the principle of confidentiality are foreseeable and have a foundation in law as distinct from mere administrative action.

72. Third, the limitations must be "*for compelling reasons within the bounds of public international laws and the international law of human rights*". There are two aspects to this requirement. The first is the exceptional nature of limitations on the principle of confidentiality: the considerations that would justify limitations must be strong, of an imperative nature. The second is that those considerations must be warranted under international law.

73. The question is: what compelling reasons under the law of international human rights would justify a limitation on the principle of confidentiality of genetic data? Broadly speaking, these are pressing public interest or social considerations, that is, reasons that would be sanctioned by international law in the public interest<sup>(15)</sup>. A reading of the relevant international instruments mentioned in the introduction would suggest that these considerations relate in particular to the administration of justice (criminal and civil), and the protection of the rights and freedoms of others, such as threat to the integrity or to the life of a person.

74. Derogation from the principle of confidentiality of genetic data are warranted in the administration of justice in the interest of public order to prevent crime and for the protection of the rights and freedoms of others. But, even in this area where there are obvious compelling social considerations, provision for disclosure should be carefully circumscribed. One uses the term "administration of justice" in its widest sense to include civil cases, where it might be necessary for a court to order disclosure, for example, in cases of identification of parenthood.

75. Available samples of biological material may be used or made available for identification of parenthood - if such is a verdict of a court. Incidental finding of non-paternity by a medical geneticist may be disclosed, only to the mother and always keeping in mind that the well being of the family and its members overrides any other consideration.

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14. For example, Article 18(3), indicates that limitations on freedom of thought, conscience and religion must be "prescribed by law and are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others".

15. See Knoppers, *supra* note 4. At page 11, speaking of privacy in the European Convention for the Protection of Human rights, she says: "States may restrict the right to privacy only where they can demonstrate some pressing social need".

## V. AWARENESS-RAISING AND EDUCATION

76. Whatever the legal safeguards and limitations that will be developed to define the boundaries of the confidentiality of genetic data, its collection, dissemination and use will continue to raise hopes for a possible cure or relief as well as fears of a possible infringement on one's free will and private life.

77. Researchers, legislators, employers and insurance companies will certainly continue to take a very great interest in all developments in this sector and do not at all need to be reminded of the importance of doing so. Whether this will be the case for the general public is a matter of doubt. This is why the Working Group considers it to be extremely important to look closely into the question of awareness and education. In its opinion, it is up to all the institutions concerned to attach the greatest possible importance to the transparent, clear and precise communication of their intentions.

78. It happens far too often, wherever there is a relationship between institutions and the citizen, that the latter is ill-informed and confronted with documents and sheets that are a closed book to him/her. Often, the person directly concerned will not dare ask for explanations for fear of revealing his/her ignorance, and will give his/her consent without really being informed of the primary or secondary uses to which the information furnished will be put. *"Freedom of consent is the freedom that brings clarity to whosoever grants it; it is also the freedom of the subject who does not suffer external constraint."*<sup>(16)</sup>

79. In a field as important as that of the use of genetic data, the extent to which information, education and counselling are needed at every step of the process cannot be over-emphasized. It is here that Articles 5, 7 and 9, and especially 21 of the Universal Declaration on the Human Genome and Human Rights take on their full meaning. In particular, Article 21 which says that States should "... take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and its applications. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions".

### Achieving Awareness

80. To achieve greater awareness in society, States should be encouraged to support the ethics councils and committees which organize information days open to the public. For example, the French National Consultative Ethics Committee for Life Sciences and Health (CCNE or *Comité consultatif national français d'éthique pour les sciences de la vie et de la santé*) organizes "National Ethics Days" for the special benefit of the general public, and more particularly for young people. For its part, the Belgian Bioethics Consultative Committee organized a public conference on 5 May 1999 on "Heredity: Genetic Tests and Society" which drew a large audience. Belgian schools carefully prepared their students to attend this event and participate in its two debates, one on "Genetic Tests and Lineage" and the other on "Genetic Tests and Law". Similarly, the European Association of Medical Ethical Centres held a conference on "Human Genetics and Laws of Bioethics" in October 1999, and one of the sessions was open to the public.

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16. Comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE), *Ethique et connaissance*. Paris: La Documentation française, 1999, page 80.

81. Indeed, it can be seen that it is very important that these questions be widely discussed so as to ward off both morbid distrust and blind confidence.

82. Raising public awareness can also prevent excessive deviations. As stressed recently by Professor A. Kahn “... *people themselves, independently of the reality of the possible prevention of an illness whose probability would have been determined by genetic tests, will likely seek to become ‘consumers of genetic testing’ ...*”<sup>(17)</sup>.

### Education

83. The need for education at all levels must be underscored. States should also encourage health sciences faculties to include classes in ethics, and especially bioethics, and communication skills courses in their curricula. This should make it possible for health care providers, particularly family doctors, as well as professional workers in the health and social sciences, who are likely to use this data, to acquire the knowledge, know-how and skills needed to provide accurate information and sufficient support to people who need to be informed about their genetic profile or about the use that will be made of the available data which concerns them. These professionals must have a clear knowledge of all questions related to the confidentiality and transmission of an individual’s or a family’s “genetic past”, as means of transmission presently available (such as electronic mail, facsimile equipment, etc.) cannot guarantee complete security. The contents and duration of these training programmes should vary according to the specialty of the professionals concerned. Furthermore, the medical ethics committees and professional licensing bodies should pay careful attention to all complaints submitted concerning the conduct of health professionals with respect to the information and support provided to patients in the field of genetics. The same approach applies to professionals in other social sciences in which such data is used. States are thus invited to adopt appropriated mechanisms to meet these needs.

### Genetic Counselling

84. The decisions to be taken in genetics relate to the heredity of families and have very important social, psychological and ethical implications. “*We have achieved greater control over certain phenomena which hitherto were beyond our scope, and are therefore now able to make choices in this field. This is why it is necessary to take unprecedented decisions for which we are ill-prepared .... There is an imperative need to propose a form of psychosocial supervision that will help in the psychological management of genetic risk.*”<sup>(18)</sup>

85. Individuals and families, therefore, before undergoing genetic tests, should be informed of the issues of confidentiality that might arise. “*This approach minimizes psychological shock and hasty decisions. Pre-test counselling should include the information that in some cases test results may be ambiguous or conflicting. ... Counsellees should also be informed before testing about any employers, insurers, other institutional third parties, government agencies, or others who in many countries may lawfully seek access to or be able to require access to their test results. Counsellees should be informed in advance of the clinic’s policy on disclosure to relatives at genetic risk and relevant laws and regulations.*”<sup>(19)</sup>

86. It is clear that genetic counselling will have an influence on the decisions which will be taken. It is here that transparency and honesty, as well as the training of the professionals, will play a role. For example, a professional who seeks recognition for

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17. *Ibid.*

18. *Gènes, générations et société: l’hérédité humaine.* Leuven: Human Genetic Centre, Catholic University of Leuven, 1999, page 25.

19. Wertz D.C.; Fletcher J.C. and Berg K. in: *1995 WHO Guidelines, supra*, pp. 37-38.

research work or is drawn by the lure of gain might provide partial and biased information to a client who could then take a decision that he might regret.

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87. In conclusion, it must be repeated that the march of progress is not going to come to a halt and that it is to the extent that States prepare and support the political strategies and programmes needed to properly educate and transparently inform professional workers and society that we will be able to avoid the worst and benefit from the best. In the words of Madame Noëlle Lenoir: *“Now it seems to me, as Benjamin Constant said, that ‘publicity is the best guarantee against arbitrariness’.* *Indeed, it is important that citizens be capable of understanding scientific progress and that science in a way should nourish society. This is a question of democracy, since it is for citizens and their representatives to make the choices dictated by these developments. As Jean-Pierre Changeux pointed out, ‘this indispensable work of informing the public is achieved through education to which ethics committees contribute at their level and in their way’.* *It is therefore necessary to do everything to prevent a gap between society and the world of research from becoming wider”*<sup>(20)</sup>.

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20. Conclusion of the Symposium *“Bioéthique et droits de l’homme”* organized by the Interministerial Mission on Human Rights (Caen, France, 23-24 October 1998), page 13.



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