NATIONAL BIOETHICS COMMISSION

RECOMMENDATION

ON THE COLLECTION AND USE OF GENETIC DATA

The National Bioethics Commission met upon invitation by the President thereof on January 25th, February 8th, March 8th, April 5th, May 17th, June 10th and September 16th 2002 in order to consider the ethical and social issues within its jurisdiction which arise from the collection and use of genetic data and to formulate a proposal on the matter pursuant to article 10 of Act 2667/1998.

The Commission:

- Having already issued an expert opinion on the use of genetic data in criminal proceedings,
- Considering the constantly expanding use of genetic data in healthcare for diagnostic, preventive and therapeutic purposes,
- Recognizing the fundamental importance of genetic research for the comprehension of genome function and evolution,
- Taking into consideration the international interest incited by the announcement of human genome sequencing and its forthcoming practical applications,
- Having in mind that the current technological capacity for rapid collection and extensive diffusion of genetic data may lead to undesirable social consequences, especially discrimination based on a person's genetic makeup,
- Acknowledging that genetic data should be protected insofar as they characterize identifiable persons,
- Sharing the concerns expressed on international level by organizations, governments and bioethics committees about the lack of relevant legislation to keep in pace with the progress of events,

has drawn up the following proposals to determine the basic rules on this issue.

A. Consent

1. General Principle

Respect for the value of human beings requires the free and informed consent of the person whose biological sample is collected for the purpose of genetic testing. In order to ensure genuine conditions of free will, the information should be provided, if possible, in advance of seeking the consent.

2. *Content of information prior to consent*

a) The purpose of the test should be adequately explained in comprehensible language,
b) It should be clarified whether the genetic data will be destroyed or stored after the test; in case they are stored, whether they will be anonymous or confidential as well as whether they are destined to commercial exploitation,
c) It should be clarified whether the biological sample will be destroyed or stored after the test; in case it is stored, whether it will be linked to the resulting genetic data or not.

3. *Warrants for the protection of confidentiality or anonymity*

The information should include specific warrants ensuring the protection of confidentiality or anonymity of biological samples or genetic data. It should be pointed out - and the person concerned should be thus advised - that for certain genetic conditions associated with visible phenotypes, anonymity cannot be ensured.

4. *Form of Consent*

The consent must be written, specific and revocable at any time before the onset of sample or data processing.

5. *Future research on anonymous samples or genetic data*

Renewal of consent is not required for future uses of anonymous samples or genetic data since privacy is ensured by anonymity.

6. *Future research on confidential samples or genetic data*

The use of confidential samples or genetic data in future similar research is covered by the initial consent provided the person concerned was informed accordingly. This information is essential for the purpose of personal data protection since the identity of the person concerned can be determined at any time.
Any use of confidential samples or genetic data in future research unrelated to the object for which the initial consent was given, requires a new consent following *ad hoc* information provided the person concerned explicitly stated so in the initial consent.

7. *Research on population groups*

The use of genetic data resulting from population genetic research also requires the prior informed consent of each member individually.
In order to facilitate the planning of such research projects, a collective consent may be sought; however, every member reserves the right not to participate.

8. *Prohibition of hierarchical orders to conduct research in specific cases*

Any hierarchical orders or pressures whatsoever by supervising authorities to carry out population genetic research in facilities associated with mandatory attendance or confinement where special power relations prevail – such as army camps, schools, prisons, etc. – should be ruled out.

B. Disclosure

1. The right to know and the right not-to-know

Everyone, in the context of self-determination, have the right to know the results of any medical, diagnostic or preventive genetic tests they were subject to. However, the right not to know is also acknowledged upon explicit request by the person concerned.
In case the results of genetic tests involve the health of third persons:

a) any person exercising their right to know must also assume responsibility for informing any third persons involved;
b) in case people exercise their right not to know, the physician may inform third persons, if absolutely necessary, in the context of the general medical obligation to care for human life (Code of Medical Ethics, article 9).
Exceptionally, the right to know the results of genetic tests cannot be exercised in the context of research projects when the interpretation of results is uncertain.

2. Disclosure of genetic data to third parties: general principle

Everyone has the right to determine whether their genetic information is to be disclosed or not to third parties as well as the content of such information and the time of disclosure.

3. Disclosure of genetic data in the context of labour relations

The Commission believes that disclosure of genetic information to employers is unacceptable even with the consent of employees or applicants. This solution is justified by the usually unequal position of employees vis-à-vis employers.

The Commission recognizes the following two exceptions from the above general rule: a) in case specific working conditions may trigger the development of genetic disease, employers may be allowed access to related genetic information with the consent of employees or applicants provided there are no alternative protective measures, and, b) in case a given occupation puts the safety of third persons at risk, employers may ask the performance of genetic tests and the communication of their results in order to guarantee the safety of the third persons involved.

The Commission recommends the adoption of specific legislation on disclosure of genetic information in the context of labour relations establishing the principle of prohibition and specifying possible exceptions.

4. Disclosure of genetic information in the context of insurance

The Commission considers that disclosure of genetic information to public social security funds is unacceptable even with the consent of the insured or prospective insured. This solution is justified by the nature of social security as public good which should be made available to all without discrimination.

As far as private insurance is concerned, disclosure of genetic information remains unacceptable when the insured or prospective insured is not covered by public social security. This solution is justified by the unequal position of the insured vis-à-vis the insurer.

However, when private insurance is complementary to social security, disclosure of genetic information is allowed provided the insured or prospective insured consents in accordance with the principle of freedom of contract.

C. Specific matters

1. Genetic tests on embryos

The Commission considers that the value of human life is independent from genetic makeup. Therefore, the Commission believes that genetic tests conducted on embryos either *in vitro* or *in vivo* should be allowed only in exceptional cases, i.e. when it is highly probable that the embryo is affected by a severe genetic disorder which will be manifested immediately after birth or in the early years of life and for which there is no adequate treatment.

The Commission stresses that the acceptance of embryo genetic testing by future parent/s is independent from their decision on the future of the embryo.

The Commission endorses the principle of equal treatment of embryos with different genetic makeup provided it does not lead to manifestation of the disease for which genetic testing was performed.

2. Genetic tests on population groups

The Commission considers that, in order to protect freedom of research and avoid social discrimination, genetic tests on population groups should be conducted in accordance with research protocols approved by a responsible bioethics committee specifically established to that purpose.

3. Storage of biological samples and genetic information

With respect to storage of biological samples, the Commission believes that storage must be governed by clear operation rules ensuring in particular that only authorized persons may access the stored samples and specifying the time of preservation of identifiable samples.

The Commission underlines that storage of records with identifiable genetic information should be covered by a licence granted by the Personal Data Protection Authority in compliance with the relevant laws on treatment of sensitive personal data.