Regulations on the Keeping and Utilisation of Biological Samples in Biobanks num. 134/2001

SECTION I
SCOPE AND DEFINITIONS

Article 1. Scope

These regulations apply to the collection of biological samples, their storage, handling, utilization and preservation in biobanks.

Article 2

In these Regulations the following terms have the following meanings:

1. *Biological sample*: organic material from a human being, alive or deceased, which may provide biological information about him/her.

2. *Biobank*: a collection of biological samples which are permanently preserved.

3. *Scientific study*: a study whose primary aim is to add to knowledge, with the purpose among other things of improving health and curing disease.

4. *Clinical test*: test carried out in order to provide health service to an individual.

5. *Free, informed consent*: consent granted in writing of a person's own free will, after the donor of a biological sample has been informed of the purpose of taking the biological sample, its usefulness, risks attendant upon the process, and that the biological sample will be permanently preserved for use under the terms of article 9 of Biobanks Act num. 110/2000.

6. *Assumed consent*: Consent that consists in the donor of a biological sample not expressing any unwillingness for a biological sample taken from him/her for a clinical test to be permanently preserved in a biobank for use by the terms of article 9 of the Biobanks Act, num. 110/2000, information in writing on this possibility having been available to him/her.

7. *Donor of a biological sample*: A person from whom a biological sample is taken.

8. *Licensee*: Individual or institution granted a licensee by the minister to operate a biobank under the terms of article 4 of the Biobanks Act num. 110/2000.

9. *Temporary preservation of biological samples:* Storage for up to five years of biological samples collected for clinical tests, treatment or specific scientific study, unless the National Bioethics Committee grants authority for a specified extension period.

SECTION II
ESTABLISHMENT AND OPERATION OF BIOBANKS

Art*icle 3. Establishment and Operation*

Establishment and operation of a biobank is only permissible by those

who have received a licensee from the minister under the terms of Biobank Act num. 110/2000. A licensee to establish and operate a biobank is contingent upon the criteria stated in arts. 5 and 6 of the Biobanks Act num. 110/2000 being fulfilled.

The majority of the board of a biobank as provided in article 6 of the Biobanks Act num. 110/2000 shall have specialized knowledge in the professional field of the biobank.

Facilities for storage of the biobank shall be consistent with the guidelines of the director of Public Health.

SECTION III
OBLIGATION TO PROVIDE INFORMATION

Article 4. *Biological Samples Gathered for Storage in a Biobank for Scientific Study*

Before a biological sample is gathered on the basis of informed consent as provided in paragraph 1 article 6, the donor of the biological sample shall be provided with information on:

a. The name and address of the person answerable for the biobank.

b. Objectives of taking the biological sample, and its usefulness.

c. The nature of the biological sample to be taken.

d. Risks attendant upon taking the sample.

e. That the biological sample will be preserved in a biobank for use according to the terms of article 9 of the Biobanks Act num. 110/2000, the content of the article being explained to the donor of a biological sample.

f. Security measures applying to the taking and preservation of the biological sample, and the nature of personal identification pertaining to them.

g. To whom the biological sample will be entrusted.

h. That he/she is free to grant authority for the preservation of the biological sample in a biobank, and that refusal to grant such authority will have no effect upon his/her legal rights.

The rules of procedure of the biobank shall be available to the donor of a biological sample.

The donor of a biological sample shall be made aware that he/she can at any time withdraw his/her consent for gathering a biological sample, and for the biological sample to be preserved in a biobank. It shall also be made clear to the donor that he/she may at any time cease participation in a scientific study. The significance of this shall be explained to him/her, cp. article 7 of these regulations.

Article 5. Biological Samples Gathered for Clinical Tests

The director of Public Health shall publicize the terms of the Biobanks Act num. 110/2000, the provisions on presumed consent under item 6 article 2, and on withdrawal of presumed consent under paragraph. 4 article 7 of the above-mentioned Act. He shall also provide information on how notice is to be given of opting-out, for registration as provided in article 10 of these regulations, and he shall undertake the production of information material and forms for giving such notice, and ensure that these are on display at health institutions, on the

premises of self-employed health workers, and in other places where biological samples are taken.

Before a biological sample is taken for clinical tests or treatment, health workers shall draw the attention of the donor of the biological sample or his/her guardian to information provided by the director of Public Health, cp. paragraph. 1. Should the donor of a biological sample be temporarily incapable of receiving such information, he/she shall be given the information when he/she is able to understand it; otherwise the information shall be provided to the next of kin.

SECTION IV
CONSENT OF DONOR OF A BIOLOGICAL SAMPLE, AND WITHDRAWAL OF CONSENT

Article 6. Informed Consent for Preservation of Biological Samples in a Biobank and for Scientific Study

The free, informed consent of the person who gives the biological sample shall be sought, cp. item 5 article 2, when a biological sample is gathered for preservation in a biobank for a specified scientific study and/or subsequent scientific studies which are consistent with the objective of the biological sample being taken.

A scientific study may not be carried out on biological samples which have been gathered for preservation in a biobank unless the study has previously received the consent of the National Bioethics Committee, and unless the terms of Act num. 77/2000 on protection of individuals with regard to the processing of personal data are fulfilled.

Article 7. Withdrawal of informed consent

A donor of a biological sample may at any time withdraw his/her consent for the preservation of a biological sample in a biobank and/or participation in a scientific study. He/she shall inform the person answerable for the study of the collection of samples of his/her decision. The answerable person shall give the donor written confirmation of the withdrawal. The person answerable for the study or collection of samples shall inform the National Bioethics Committee and the Data Protection Authority of the withdrawal of consent. When a donor of a biological sample has withdrawn his/her consent as provided in paragraph. 1 article 7 of the Biobanks Act num. 110/2000, the biological sample shall be destroyed.

On withdrawal of informed consent, the biological sample shall be destroyed, *i. e.* samples of tissue, blood samples, cells and isolated genetic material (DNA/RNA), and it is not permissible to carry out further tests on the sample, whether the original biological sample or isolated parts of it, cells or genetic material.

The results of studies already carried out, based upon the use of the biological sample of the person who has withdrawn consent, shall not, however, be destroyed, but shall be stored in non-personally-identifiable form, so that it is not possible to trace the results to the donor. Results of studies shall be results of all kinds; written text, numerical values, measurements, graphs and pictures. Also results that contain molecules or molecule fragments (including those from

nucleic acids or proteins) in the form of stripes or spots in gel, on membrane or on glass slides. Their use for further research is not permitted.

The results of studies originating in biological samples, such as tissue cultures, gene sequences, isolated genes or isolated molecules, original or mutated, shall not be destroyed, but all personal identification shall be removed, so that they cannot be traced back to the donor.

With regard to security of personal data, the rules laid down by the Data Protection Authority shall apply. cp. mainly item 8 article 5 and paragraph. 1 article 12 of the Biobanks Act num. 110/2000.

Article 8. Presumed Consent for Clinical Tests

Should biological samples have been gathered in connection with clinical tests or treatment, the presumed consent of the donor of the biological sample may be assumed, cp. item 6 article 2, for the biological sample to be stored in a biobank, provided that this is stated in written information which is available to the donor of a biological sample where the sample is taken, cp. paragraph. 2 article 5 of these regulations.

A biological sample from a deceased person may be stored in a biobank, provided that he/she has not withdrawn consent prior to his/her decease. Otherwise the terms of the Biobanks Act num. 110/2000 shall apply to biological samples from deceased persons.

Surviving relatives have no rights over biological samples of the deceased. Should the use of samples be a matter greatly affecting the interests of the surviving relatives, the National Bioethics Committee may decide that they shall be informed, and that their views be solicited.

Article 9. Withdrawal of Assumed Consent

A donor of a biological sample may at any time withdraw his/her assumed consent for a biological sample to be stored in a biobank for use under the provisions of article 9 of the Biobanks Act num. 110/2000, whether with regard to all biological samples or a specific sample, to all studies or a specific study. Such a request must be complied with.

On withdrawal of assumed consent, the biological sample shall not be destroyed, but preserved for use in the interests of the donor of a biological sample. When access is provided in accord with the above, a record shall be kept. Other use is contingent upon the donor's specific permission, but see also paragraph. 4.

The donor of a biological sample shall inform the director of Health of his/her wish. The director of Health shall prepare forms for giving such notice, and ensure that they are displayed at health institutions, on the premises of self-employed health workers and at other places where biological samples are taken.

With regard to the security of such data, regulations laid down by the Data Protection Authority, as provided in item 8 paragraph. 1 article 5 of the Biobanks Act num. 110/2000, shall apply.

A biobank board may, in exceptional circumstances, with the permis-

sion of the Data Protection Authority and the National Bioethics Committee, authorize use of biological samples for other purposes than that for which they were taken, provided that important interests are at stake and that the benefit outweighs possible inconvenience to the donor of a biological sample, or other parties.

SECTION V
REGISTERS OF PERSONS WHO HAVE OPTED OUT

Article 10. Register of those who have opted out and arrangements

The director of Health shall ensure that the wishes of the donor of a biological sample with regard to withdrawal of consent are respected. He shall maintain a coded register of donors who have opted out, which shall always be available to the boards of biobanks. The register shall contain only those data necessary to the work of the bank, and to ensure that the wishes of the donor of a biological sample are respected.

When access to a biobank is sought for purposes of scientific study, the party answerable for the bank shall gather information on those who have opted out, before access to biological samples in the bank is authorized.

Staff of the director of Health who are employed in the above work are subject to confidentiality regarding matters of which they become aware in their work, which should be kept confidential, by law or by their nature. They shall sign an oath of confidentiality before commencing employment. The obligation of confidentiality remains in force after employment ceases.

SECTION VI
ACCESS TO BIOBANKS FOR SCIENTIFIC STUDY

Article 11. Obligations of Biobank Boards

When access is granted to a biobank, the bank board shall ensure that the access for purposes of scientific study does not adversely affect the possibility of further diagnosis of disease in the interest of the donor of a biological sample.

Before access to a biobank is granted by the terms of article 9 of the Biobanks Act num. 110/2000, a research protocol shall exist, that has been approved by the National Bioethics Committee or the ethics committee of the relevant health institution, cp. Regulations num. 552/1999 on scientific studies in the health sector. In the case of a genetic study, the informed consent of the person in question shall normally be sought if he/she is alive, and always if the data can be traced back to a certain individual, and this shall be subject to the judgement of the Bioethics Committee and the Data Protection Authority. The criteria laid down by the Data Protection Authority, under the provisions of the Act on protection of individuals with regard to the processing of personal data, shall be met.

In biobanks which have come into existence at public health institutions or other publicly-funded institutions, the bank board shall, in the making of agreements with scientists, maintain consistency and fairness in the granting of access to the biobank. Access to a biobank shall be based upon professional and scientific criteria, taking into account the interests of the donor of a biological sample.

The biobank board shall give substantiated reasons for refusing a request for access.

A biological sample may be sent out of the country in the interests of the donor of a biological sample, for purposes of diagnosis or for quality control. Other transportation of biological samples out of the country is subject to the approval of the National Bioethics Committee and the Data Protection Authority, and on conditions laid down by them. Samples shall normally be sent without personal identification. The person answerable for the study is responsible for samples being sent without any personal identification, and for remnants of the samples being returned at the end of the study.

A bank board may not transfer a biological sample to another biobank without the permission of the National Bioethics Committee and the Data Protection Authority, and on the conditions laid down by them.

The bank board may preserve at the biobank special collections of biological samples which have been gathered for a specific study; access to these shall be in accord with an agreement made with the person answerable for the study, with the permission of the National Bioethics Committee and the Data Protection Authority, and on the conditions laid down by them.

SECTION VII
OPERATION OF BIOBANKS

Article 12. Obligation to Provide Information

Biobanks shall supply on request standardized information on the following factors:

1. Names and addresses of members of the bank board, and the person answerable for the biobank.
2. Who is responsible on a daily basis for the biobank.
3. Objectives of operating the biobank.
4. Types of biological samples.
5. Origin of biological samples.
6. Who has access to the biological samples, and whether transfer of samples out of the country is possible.
7. Where the biobank's rules of procedure are available.

Article 13. Public Register of Biobanks in Operation

The director of Health shall maintain a register of those biobanks which have received an operating license from the minister of Health. This shall include at least the information specified in article 12. The register shall be available to the public on the website of the director of Health.

Article 14. Donor's Right to Information

At the request of a donor of a biological sample, the director of Health or the biobank board must provide the donor with information on the following matters with regard to his/her biological samples:

1. Whether biological samples from him/her are kept in a biobank, and if so the nature of the samples.
2. For what purpose the sample was taken.
3. Who has had access, or may have access, to the biological samples.
4. On what grounds such access is granted.

5. What security measures apply to gathering and storage of the biological samples.

SECTION VIII
VARIOUS PROVISIONS

Article 15

Amendments to these regulations shall be made in consultation with the National Bioethics Committee, the Data Protection Authority and the director of Health.

Article 16. Entry into Force

These regulation are issued on authority in article 9 and 16 of the Biobanks Act num. 110/2000, and shall take force immediately.