各國基因資料庫法規彙編

冰島編

各國基因資料庫法規彙編（冰島編）

台灣地區生物資料庫建立與多重疾病多重危險因子之世代追蹤研究

各國基因資料庫法規彙編（冰島編）

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* 資料來源：http://www.ministryofhealth.is/laws-and-regulations/nr/31，訪問日期 2006/02/21

English translation

12.09.00

Act on Biobanks

No 110/2000

SECTION I General Provisions

Art. 1

Objectives

The objective of the Act is to authorise the collection, keeping, handling and utilisation of biologicalsamples from human beings, in such a way that confidentiality is ensured, the interests of donors of biological samples is safeguarded and that the utilisation of the biological samples serves the purposes of science and medicine, and is conducive to the public good.

The interests of science and of the community shall never be given priority over the interests of the donor of a biological sample. It is prohibited to discriminate against a donor of a biological sample on the grounds of data derived from a biological sample.

Art. 2

Scope

This Act applies to the collection of biological samples, and their keeping, handling, utilisation and storage in biobanks.

The Act does not apply to temporary keeping of biological samples taken for purposes of clinical testing, treatment, or for specific scientific study, provided such samples are destroyed when the tests, treatment or research are completed. Temporary keeping means storage for up to five years, unless the National Bioethics Committee authorises a longer period of storage. Should the long-term preservation of such samples be desired, they shall be stored in a biobank.

The Act does not apply to the storage of gametes and embryos under the provisions of the Act on Artificial Procreation, to organs under the provisions of the Act on Organ Removal, or to bodily remains under the terms of the National Heritage Act.

Art. 3

Definitions.

In this Act 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 the 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 in a biobank for use under the terms of art. 9

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 art. 9, information in writing on this possibility having been available to him/her.

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

8. *Licensee*: Individual or legal entity granted a licence by the Minister to operate a biobank under the terms of art. 4 of this Act.

SECTION II **Establishment and Operation of Biobanks**

Art. 4

Authority to Found and Operate a Biobank

The establishment and operation of a biobank, i.e. collection, keeping, handling, utilisation and storage of biological samples, is permissible only for those who have been granted a licence from the Minister under the provisions of this Act, following the receipt of recommendations from the Director General of Health and the National Bioethics Committee.

Art. 5

Conditions of Licence

A licence for the establishment and operation of a biobank is contingent upon he following conditions:

1. The terms of this Act, and government directives on the basis of the Act, shall be complied with.
2. The biobank shall be located in Iceland.
3. The objectives of the operation of the biobank, and the operational basis of the bank, shall be clearly defined.
4. Conditions of storage for biological samples shall be described.

5. Protocols of the biobank shall have been drawn up, including regulations of the biobank on arrangements for collaboration with foreign parties.

6. A governing board shall be nominated, as provided in art. 6, and one individual shall be nominated to be answerable for the biobank.

7. The answerable party for the biobank shall be a physician and shall have practised independent research and development work within the health sector. In the case of the biobank comprising exclusively biological samples gathered for purposes of scientific study, the answerable party is not required to be a physician.

8. That evaluation of security, and security measures in gathering of biological samples, shall be consistent with the rules laid down by the Data Protection Authority on security of personal data in biobanks.

   The Minister may lay down further conditions.

Art. 6

Board of a Biobank

The licensee shall appoint a board of at least three people for each biobank, which shall monitor its operations. The board shall be under an obligation to keep the Director General of Health, the Data

Protection Authority and the National Bioethics Committee informed regarding the biological samples and operations of the biobank.

SECTION III **Collection, Handling and Access to Biological Samples**

Art. 7

Consent of Donor of a Biological Sample and Withdrawal of Consent

In connection with collection of a biological sample for preservation in a biobank, the free, informed consent of the person giving the biological sample shall be sought. This consent shall be given freely and in writing after the donor of a biological sample has been informed of the objective of the sample collection , the benefits, risks associated with it's collection , and that the biological sample will be permanently stored at a biobank for use as provided in art. 9. In addition the provisions of Art. 20 of the Act on personal privacy and handling of personal data shall be observed where applicable.

A donor of a biological sample can at any time withdraw his/her consent under the terms of para. 1, and the biological sample shall then be destroyed. Material that has been produced from a biological sample by performance of a study or the results of studies already carried out shall, however, not be destroyed.

If biological samples have been collected for the purpose of clinical tests or treatment, the consent of the patient may be assumed

for the storage of the biological sample in a biobank for use as provided in art. 9., provided that general information on this is provided by a health care professional or health institution.

A donor of a biological sample may at any time withdraw his/her assumed consent for his/her biological sample to be stored in a biobank for use as provided in art. 9, in which case it shall thereafter only be used in the interests of the donor of a biological sample or by his/her specific permission , but see also para. 4 art. 9. The request of a donor of a biological sample'may apply to all biological samples which have been taken or may be taken from him/her. Such a request must be complied with. The donor of a biological sample shall inform the Director General of Health of his/her request. The Director General of Health shall be responsible for preparation of forms for giving such notice, and shall ensure that these are available at health institutions, and at the premises of self-employed health care professionals. The Director General of Health shall ensure that a coded register of those who have opted out in this way shall always be available to the boards of biobanks. Staff of the Director General of Health who carry out this work are subject to an obligation of confidentiality regarding information they may become aware of in the course of their work, which should remain confidential by law or by its nature. Such staff shall sign an oath of confidentiality before their employment begins. The obligation of confidentiality remains in force after employment ceases.

Art. 8

Preservation of Biological Samples

Biological samples shall be kept securely and labelled, but stored without personal identification. The linking of biological samples with personal identification shall be in keeping with standards laid down by the Data Protection Authority.

Biological samples shall be stored in such a way that they are not lost or damaged, and that they are not accessible to those who are not entitled to use them.

Should the licensee decide to cease operation of the biobank, the licence having been revoked as provided in Art. 14, the Minister shall, after receiving recommendations from the Director General of Health, the Data Protection Authority and the National Bioethics Committee, decide on the future of the biobank, taking into account the wishes and proposals of the licencee.

Art. 9

Access to Biobank and Use of Biological Samples.

Biological samples shall be acquired for clearly defined and lawful purposes, and not used for other purposes, but see para. 2, 3 and 4.

The answerable party for the biobank grants access to biological samples for further diagnosis of diseases. He/she may also grant access to biological samples for purposes of quality control,

development of methods and tuition, provided that they are not personally identified.

The board of the biobank shall negotiate with scientists on access to biological samples. Access to biological samples for scientific studies may not, however, be granted until the permission of the Data Protection Authority has been granted on the basis of the Act on personal privacy and handling of personal data, and a research protocol has been approved by the National Bioethics Committee or the ethics committee of the relevant health institution, as provided in the Act on the Rights of Patients and of regulations issued on the basis of the Act.

The board of the biobank may, if approved by the Data Protection Authority and the National Bioethics Committee, authorise the use of biological samples for other purposes than those for which the samples were originally collected, provided that important interests are at stake, and that the potential benefit outweighs any potential inconvenience to the donor of a biological sample or other parties.

The Minister shall, having received proposals from the Director General of Health, the National Bioethics Committee and the Data Protection Authority, issue regulations defining more precisely the use of biological samples.

Art. 10

Rights and Fees

The licensee shall not be counted as the owner of the biological samples, but has rights over them, with the limitations laid down by law, and is responsible for their handling being consistent with the provisions of this Act, and of government directives based on it. The licensee may thus not pass the biological samples on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt.

The licensee may take a fee for a biological sample, or access to a biological sample, equivalent to the cost of gathering, storage and access to the sample. Any further fee is prohibited.

A biological sample may be sent out of the country in the interests of the donor of a biological sample, for diagnosis or quality control. Other transportation out of the country of biological samples is subject to the approval of the National Bioethics Committee and the Data Protection Authority and on the conditions they lay down.

Art. 11

Confidentiality

All staff of biobanks and those who have access to them shall preserve confidentiality regarding matters relating to their work which should be kept confidential, by law or by their nature. The obligation

of confidentiality remains in force after employment, research or tuition ceases.

SECTION IV **Monitoring and Obligation to Supply Information**

Art.12

Monitoring

The answerable party for the biobank shall be responsible for the implementation of internal monitoring and that security assessments be carried out regularly, in accord with the provisions of arts 11 and 12 of the Act on personal privacy and handling of personal data.

The Data Protection Authority shall monitor the security of personal data in biobanks. The Data Protection Authority's monitoring of biobanks is subject to the terms of para. 4 art. 35, paras. 2 and 4, art. 37 and arts 38-43 of the Act on personal privacy and handling of personal data.

The Director General of Health shall monitor biobanks in so far as this monitoring does not fall within the ambit of the Data Protection Authority or the National Bioethics Committee.

Art. 13

Obligation to Supply Information: Government and Biobank Boards

The Director General of Health is under an obligation to promulgate in detail to the general public the terms of this Act on

biobanks, especially the provisions on assumed consent of a donor of a biological sample regarding a clinical test, and also the rights of the individual by the terms of art. 7 and of para. 3 of the article.

The Director General of Health shall annually issue a register of biobanks, their purposes, activities and protocols. The register shall contain information on the membership of the board of each bank, and the identity of the answerable party. This register shall be made public and shall be accessible to the general public.

The board of the biobank or the Director General of Health is obliged to provide individuals with information on whether biological samples from him/her are stored in a biobank, and on the nature of such biological samples.

SECTION V **Penalties**

Art. 14

The Minister may revoke the licence under the terms of this Act, if the licensee or its employees violate the terms of the Act or government directives on the basis of the Act, if the conditions of the licence are not fulfilled, or if the licensee proves unable to operate the biobank. Should the licensee violate the terms of this legislation or not comply with the conditions of the licence, the Minister shall give the licensee a written warning, allowing a reasonable period of grace to rectify matters. Should the licensee not comply with such a warning,