Ministry of Health and Social Affairs, Sweden

Biobanks in Medical Care Act (2002:297)

Promulgated:
23 May 2002

Date of entry into force:
1 January 2003

Date of translation:
March 2003

Content

Chapter 1. General provisions

The purpose of the Act

Section 1
This Act regulates how human biological material is to be collected, stored and used for certain purposes with respect for the personal integrity of the individual.

Definitions

Section 2
This Act uses the following terms and definitions.

Term	Definition
Biobank	Biological material from one or more human beings that is collected and preserved for an indefinite or limited period, and whose origin is traceable to an individual or individuals.
Research Ethics Committee	Special entity that considers issues of research ethics, and includes representatives from both the general public and the research community, and has a link to a university, university college or some other institution that substantially engages in the funding of research activities.
Entity responsible for a biobank	Care provider, research institution or other entity that maintains a biobank.
Medical care	Activity operating under the provisions of the Health and Medical Service Act (1982:763) or the Dental Care Act (1985:125).
Human being	Person, living or dead, or embryo.

Donor	Living person from whom tissue samples have been collected.
Care provider	Physical person or legal entity providing medical care on a professional basis, or a laboratory that receives tissue samples from care providers and which preserves the specimens in a biobank.
Tissue samples	Biological material from human beings.

Area of application

Section 3
The Act applies to

1. Biobanks that are established in Sweden as part of a care provider's medical activities, irrespective of where the material in the biobank is stored, and

2 Tissue samples from a biobank as indicated in 1 that are released for storage and use on the premises of another care provider, an institution for research or diagnostics, a public research institution, a pharmaceutical company or other legal entity, and which after the release are traceable to the person or persons from whom they originate.

Relevant parts of the Act shall apply for tissue samples taken and collected for transplant purposes in accordance with the Transplants Act (1995:831).

The Act does not apply to specimens that are routinely collected in the course of medical care for analysis, and which are solely intended to form the basis of a diagnosis and the ongoing care and treatment of the donor, and which are not stored for a long period.

Relation to provisions in other legislation

Section 4
Provisions in other legislation that deviate from the provisions in this Act shall apply with the exception that the provisions in chapter 5 concerning the PKU register shall take precedence over provisions in other legislation.

Chapter 2. Establishment and conditions

Establishment

Section 1
A biobank is established through a decision by a care provider or some other person or entity to whom tissue samples from a biobank are released in accordance with the provisions in chapter 1, section 3, clause 2. When a decision is made to set up a biobank, the entity responsible for that biobank shall also decide on the purpose(s) for which the biobank shall be used, and appoint a person to be responsible for the biobank.

Permitted purposes

Section 2
Biobanks are to be used by a care provider for care and treatment and other medical purposes. The only other permitted uses of a biobank are for quality assurance, training, research, clinical trials, development or other equivalent activities.

Research and clinical trials

Section 3
A decision to allow a biobank to be used for purposes of research or clinical trials, pursuant to section 1, may not be made until the matter has been considered and approved by a research ethics committee. In these cases, the biobank may not be used for purposes other than those previously decided unless approved by the committee.

Storage

Section 4
A biobank shall be stored in such a way that there is no risk of the tissue samples being destroyed or of unauthorised persons gaining access to them.

Notification

Section 5
The entity responsible for a biobank shall notify the National Board of Health and Welfare of a decision to establish a biobank. The notification shall include information regarding
– the purpose of the biobank,
– the storage location of the biobank,
– the person responsible for the biobank, and
– the scope of the biobank.
The notification shall be made within one month of the decision to establish the biobank.

Any change from a previous notification shall be reported to the National Board of Health and Welfare within one month of the change being implemented.

A decision to place tissue samples stored in a biobank at the disposal of anyone other than the Supervisory authority shall be reported within one month of the decision.

Register of biobanks

Section 6
The National Board of Health and Welfare shall keep an automated register of biobanks. The register shall be used for supervision, research and to produce statistics.

The register shall contain details of the conditions that must be reported pursuant to section 5. The register may not contain any particulars about individuals from whom the samples have been collected.

The National Board of Health and Welfare is responsible for the personal data in the register.

Chapter 3. Consent and information

Donors

Section 1
Apart from cases specified in section 2, tissue samples may not be collected and preserved in a biobank without informing the donor of that intention and about the purpose(s) for which the biobank may be used, and obtaining his or her consent.

Minors

Section 2
Tissue samples may not be collected from minors and preserved in a biobank without informing the parent or guardian of the minor of that intention and about the purpose(s) for which the biobank may be used, and obtaining the consent of the parent or guardian. If the minor has reached such an age and level of maturity that he or she can make a decision on the matter, the above provisions shall apply to the minor.

Embryos and foetuses

Section 3
Tissue samples may not be collected from an embryo or foetus and preserved in a biobank without informing the mother who is bearing or has borne the embryo or foetus of the intention and about the purpose(s) for which the biobank may be used, and obtaining the mother's consent. If the woman is deceased, this provision shall apply to her next of kin.

Deceased persons

Section 4
The Transplant Act (1995:831), sections 3 and 4, and the Autopsy Act (1995:832) apply to tissue samples from deceased persons.

New purpose

Section 5
Tissue samples preserved in a biobank may not be used for other purposes than those indicated in information submitted previously for which consent has been granted. In the event of a new purpose, the person who previously granted consent must be informed about the new purpose and grant new consent.

If the person who originally granted the consent has deceased, the deceased's next of kin shall be informed of the new purpose and, after a reasonable period of reflection, must not be opposed to the new purpose.

If the new purpose is research or clinical trials, the research ethics committee that approves the new purpose shall also determine the requirements concerning the information and consent regulations that shall apply so that the tissue samples in the bank may be used for the new purpose.

(2002:297)

Withdrawal of consent

Section 6
A person who has granted consent for the use of a tissue sample may withdraw the consent at any time. If the withdrawal of consent refers to all use, the tissue sample shall be immediately destroyed or depersonalised.

Documentation

Section 7
Records of information and consent, etc, pursuant to sections 1–6, shall be suitably documented.

The Patient Records Act (1985:562), Section 3, contains special provisions regarding this type of documentation.

Chapter 4. Provisions on the release of tissue samples, transfer of biobanks, etc.

Release of tissue samples from a biobank

Section 1
The person responsible for a biobank considers applications for access to the specimens in the bank but must leave decisions on the matter to the supervisory authority.

Section 2
When tissue samples are released for storage and use in another institution in accordance with chapter 1, section 3 clause 2, the entity responsible for a newly formed biobank shall make a decision in accordance with chapter 2 section 1. Specimens stored in such a biobank may not be released to third parties.

Section 3
If tissue samples in a biobank are to be released to a recipient in another country for research purposes, a Swedish research institution must submit an application. If this application is approved, a condition shall be placed on the recipient in the foreign country that the specimens are to be returned or destroyed when they are no longer needed for the purpose for which they were released.

Tissue samples in a biobank may only be released to a recipient in another country under the conditions described in the first clause of this section.

Depersonalisation and code keys

Section 4
Released tissue samples shall be depersonalised or coded, unless otherwise decided.

Code keys shall be kept on the premises of the care provider who decided to collect and store the tissue samples in a biobank. The code keys shall be stored securely.

An application to break a code to gain access to personal details about an individual donor shall be considered in the same way as an application for access to specimens in a biobank.

Exceptions

Section 5
Sections 1–3 do not prevent the following actions, taken with the consent of the individual donors in question:

– tissue samples in a biobank that are intended for care and treatment purposes may be sent to another care provider either in Sweden or abroad for comment or analysis;

– tissue samples in a biobank used in a research project may be sent to another unit for research either in Sweden or abroad;

– tissue samples that have been supplied to a company conducting clinical trials of pharmaceutical or medical technology products, and which are stored on the company's premises, may be passed on to another company within the company for analysis, or be delivered to another company with which the company has entered into an agreement on analysis, whether in Sweden or abroad.

The specimens shall be coded. They shall be returned or destroyed when they are no longer needed for the purpose for which they were released.

Refusal to release tissue samples

Section 6
If the person responsible for a biobank at the premises of a public care provider refuses to release specimens in accordance with an application, the matter shall be referred to the care provider for a decision. The applicant shall be informed of the right to request reconsideration.

If a private care provider and the person responsible for the biobank at the premises of the care provider feel that specimens from the biobank should not be released in accordance with an application, the matter shall be submitted to the National Board of Health and Welfare for consideration. The care provider's statement shall accompany the submission.

Transfer of tissue samples in a biobank

Section 7
The National Board of Health and Welfare must grant permission before a biobank or parts of it can be transferred. Permission is only given for special reasons.

A biobank or parts of it may not be transferred to a recipient in another country.

Handling tissue samples for financial gain

Section 8
Tissue samples or parts of tissue samples that are stored in a biobank may not be transferred or released for financial gain.

Conditions for closing a biobank

Section 9
Upon an application from the care provider or supervisory authority, the National Board of Health and Welfare shall decide to close a biobank and destroy its tissue samples, if the material is no longer significant for the purpose pursuant to chapter 2 section 2, and there is no reason of public interest to preserve the specimens.

However, the entity responsible for a biobank that consists of tissue samples released by a care provider's biobank, may decide that the biobank shall be closed. The specimens shall be returned to the care provider or be destroyed when they are no longer required for the purpose for which they were released.

Release of personal data

Section 10
If a donor's personal details are released at the same time as a coded tissue sample from that donor, they shall be released in such a way that the personal details cannot be connected with the tissue sample.

Section 11
A care provider shall submit personal data for entry in a register that is stored in connection with a biobank on the premises of another care provider. However, this obligation only applies if the registered person or the person who can grant consent according to chapter 3, sections 2-4, has been informed about, and explicitly consented to the submission.

Chapter 5. Biobank with specimens from newborn babies

Area of application

Section 1
Care providers that the government decides may receive, collect, store, register, analyse and in some other way have at their disposal tissue samples from newborn babies in a special biobank (the PKU biobank). This applies to those purposes indicated in Section 2.

Purpose

Section 2
The tissue samples in the PKU biobank may only be used for
– analyses and other studies aimed at detecting and diagnosing metabolic disorders,
– retrospective diagnostics of other diseases in individual children,
– epidemiological studies,
– follow up, evaluation and quality assurance of the activity, and
– clinical research and development.

Obligation to release specimens

Section 3
In compliance with chapter 3 section 2, a care provider is obliged to release such specimens as indicated in section 1 for analysis and storage in the PKU biobank.

Register

Section 4

Care providers as indicated in section 1 may employ automated or some other form of processing of personal data to maintain a special register for screening specimens from newborn babies for certain metabolic disorders (the PKU register).

The care provider is responsible for personal data in the register.

Section 5
The PKU register may only be used for those purposes indicated in section 2 and for the production of statistics.

Section 6
Only the following information may be registered for each donor:

– the mother's name, personal identity number, and town of domicile,

– length of pregnancy,

– the child's time of birth and gender, and the order in the case of a multiple birth,

– the unit within the medical service that took the specimen,

– diagnosis,

– information concerning the treatment of diagnosed diseases, and

– consent from the child's parent/guardian.

Section 7
A care provider is obliged to submit information pursuant to section 6 to the PKU register when a tissue sample is collected from a newborn baby, and the child's parent/guardian has explicitly granted consent for the submission.

Before the parent/guardian grants his/her consent, he/she shall have been informed about the information registered and the purpose of the registration.

Chapter 6. Supervision and appeals, etc.
Penalties

Section 1
Anyone who intentionally or negligently engages in the following actions will be fined:

a) uses a biobank in a way that contravenes chapter 2 section 2,

b) stores tissue samples in a biobank in contravention of chapter 2 section 4,

c) establishes a biobank without making an application pursuant to chapter 2 section 5,

d) does not provide information and obtain consent pursuant to chapter 3, sections 1-3 and 5,

e) does not destroy or depersonalise tissue samples pursuant to chapter 3, section 6,
f) releases tissue samples in contravention of chapter 4 section 2,
g) releases tissue samples in contravention of chapter 4, section 3,
h) transfers a biobank in contravention of chapter 4, section 7,
i) uses tissue samples in contravention of chapter 5, section 2,
j) does not release tissue samples pursuant to chapter 5, section 3.

Sections 15–16 of the Transplants Act (1995:831) contain provisions for penalties for anyone transferring biological material for financial gain.

Compensation, etc

Section 2

The entity responsible for a biobank shall compensate an individual donor suffering damage or violation of personal integrity as a result of tissue samples being handled in a way that contravenes this Act.

The liability for compensation can be reduced by a reasonable amount if the entity responsible for a biobank shows that he or she was not responsible for the error.

The provisions in the Personal Data Act (1998:204) concerning rectification and compensation apply to the processing of personal data pursuant to this Act or regulations that have been issued with the support of the Act.

Supervision

Section 3

The National Board of Health and Welfare shall supervise compliance with this Act. However, the supervising authority pursuant to the Personal Data Act (1998:204) shall supervise the processing of personal details.

The person running the supervised operation is responsible for supplying documents, specimens and other relevant materials when requested by the National Board of Health and Welfare in its supervisory capacity.

The National Board of Health and Welfare may order the person running the operation to release the material requested. A penalty may be imposed in the order.

Section 4

The National Board of Health and Welfare, or anyone appointed by the Board, is entitled to inspect the operation that is under supervision according to this Act.

The person conducting the inspection is entitled to access to areas, premises and other localities used for the operation, but not

residential premises, and to temporarily take custody of documents, specimens and other material relevant to the operation. The National Board of Health and Welfare may also conduct studies and take samples.
The person whose operation is being inspected is obliged to provide the help needed for the inspection.

Section 5
The person conducting the inspection is entitled to help from the police authority in order to conduct the inspection.

Section 6
If the National Board of Health and Welfare becomes aware that a person has violated a provision applying to an operation supervised by the Board pursuant to this Act, the Board shall take measures to correct the violation. If necessary, the Board shall apply for legal action.
Appeals, etc

Section 7
A decision pursuant to the first clause of chapter 4, section 6, may be appealed to the National Board of Health and Welfare. The decision of the Board pursuant to chapter 4, section 6, may not be appealed.
Other decisions of the National Board of Health and Welfare may be appealed to a public administrative court.
Decisions by another authority on rectification and on rejection of application for information pursuant to section 26 of the Personal Data Act (1998:204) may be appealed to a general administrative court.
Leave to appeal is required for an appeal to the Administrative Court of Appeal.
Decisions issued by the National Board of Health and Welfare or a public administrative court pursuant to this Act come into force immediately, unless stated otherwise in the decision.

Authorisation

Section 8
The government or an authority decided by the government may issue more detailed regulations on
– time limits for preservation of tissue samples in biobanks, and
– transfer and closure of biobanks.

---

1. This Act shall go into effect on 1 January 2003.

2. If a biobank already existing before the Act goes into effect is to be preserved, the biobank must be registered with the National Board of Health and Welfare within two years of the Act coming into effect. An application shall form the basis of the entry in the National Board of Health and Welfare's register.

3. The Act shall apply to tissue samples that were collected in a biobank before the Act shall go into effect but which are intended to be used after the Act comes into effect. A supervisory authority wishing to close a biobank existing at the time the Act comes into effect, shall be entitled to do so before the end of the time period in clause 2, without needing to comply with the provisions of chapter 4, section 9.