Ministry of Social Affairs and Health, Finland
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688/2012

Biobank Act

Chapter 1

General provisions

Section 1

Objectives

The objectives of this act are to support research that utilises human biological samples, to promote openness in the use of these samples and to secure the protection of privacy and self-determination when processing these samples.

Section 2

Scope of application

This Act contains provisions on the following:

1) the establishment of a biobank, conditions for practising biobanking activities and requirements to be met by such activities;

2) the collection in a biobank of samples and information concerning the samples or attached to the samples and the use and other processing of these samples;

3) supervision of storage and processing of the samples;

4) the rights of registered individuals and arrangements necessary to protect information;

5) registers established for the purposes of biobank research.

Section 3

Definitions

For the purposes of this Act:

1) *biobank* means a unit maintained by an operator engaging in biobanking activities for the purposes of collecting and storing samples and information associated with the samples for future biobank research;

2) *sample* means human biological material or a technical record of such material;

3) *sample with an identifier* means a sample containing information identifying a natural person or a sample that can be traced back to a natural person by the person processing the sample;

4) *coded sample* means a sample where the connection to a natural person or information concerning the sample or attached to the sample has been marked with an identifier that does not contain information identifying a natural person;

5) *code key* means information that links the identifier to the natural person referred to in section 4;

6) *unidentified sample* means a sample that has not been furnished with information identifying a natural person or samples where the link to such information has been permanently severed;

7) *registered individual* means the person from whom a sample with an identifier was taken;

8) *biobank research* means research utilising the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in health care and medical care;

9) *processing of samples* means the collection, receipt and storing of samples and information associated with them, as well as the linking and removal of information and the analysis, study, use, transfer, granting access to and destruction of samples and information and other measures directed towards the sample and information.

Section 4

Relation to other legislation

Unless otherwise provided in this act or elsewhere in law, the Personal Data Act (523/1999) is applied to the processing of personal information. The Act on the Openness of Government Activities (621/1999) is applied to the publicity, secrecy and granting of access to information in the possession of authorities, whereas the Personal Data Act is applied to other processing of personal information.

Provisions on the conditions for the performance of medical research and the ethical pre-evaluation of research plans are laid down in the Medical Research Act (488/1999).

Provisions on the conditions for the transfer of organs, tissues and cells removed in connection with a post-mortem examination, and for the purposes of diagnosing and the treating human disease or injury, to a biobank and their use in biobank research are laid down in the Act on the Medical Use of Human Organs and Tissues (101/2001).

Separate provisions shall be issued regarding the processing of samples taken for the purposes of forensic research.

Chapter 2

Establishment and operations of a biobank

Section 5

Duties of a biobank

The duty of biobanks is to provide service for biobank research.

In the performance of this duty, a biobank may:

1) collect and receive samples and information associated with them;

2) store samples and information associated with them and provide access to the samples for the purposes of biobank research;

3) analyse, study and otherwise process samples.

Biobanks publish information on samples stored by them, the use of these samples for the purposes of biobank research and the results of studies conducted by them.

Section 6

Conditions for establishing a biobank

A biobank can be established by a private person or by a public institution, community, foundation or other body corporate provided that the party in question possesses the financial and operational means necessary and meets the legal and research-related conditions for maintaining a biobank and processing samples. An operator establishing a biobank must be in possession of the personnel, facilities and equipment required by the activities.

A further condition for establishing a biobank is a positive statement from the National Committee on Medical Research Ethics. The following information and documents must be attached to the request for a statement:

1) name or other identifier of biobank;

2) owner of biobank, business name of the owner and main financiers of biobank;

3) location and method of storing the samples and information associated with them and an account of arranging the management of information in the registers;

4) description of the biobank's area(s) of research and an account of the principles and terms to be applied in the collection, granting of access to for the purposes of biobank research and other processing of samples and information associated with them and restrictions concerning the use of samples;

5) the consent form used and a model for a written report to be submitted when requesting consent or information on the content of the report and a description of submitting the report;

6) an account of whether samples and related information other than those based on consent will be stored in the biobank;

7) an account of whether samples and related information other than those owned by the biobank will be stored in the biobank and, if necessary, information on the owner of the samples;

8) an action plan that outlines the planned scale of the biobanking activities, the organisation of the activities and the division of responsibilities.

The National Committee on Medical Research Ethics must issue its statement within 60 days of receiving the request for statement referred to in subsection 2. The period of issue starts from the reception of possible additional information and clarifications requested. For its statement, the ethics committee must determine whether the activities of the biobank meet the conditions concerning the protection of privacy and self-determination laid down in this act and elsewhere in law and present a justifiable view on the ethicality of the activities.

Section 7

Requirements and decision-making concerning the activities of biobanks

The use, storing and other processing of samples to be collected in a biobank must be justified with respect to the research for which the samples will be utilised.

A biobank owns the samples in its possession, unless otherwise stipulated in an agreement on the transfer of samples.

Prior to launching operations, a biobank must compile written instructions for the processing of samples, data protection and information security and describe procedures for supervising compliance with these instructions.

Decisions concerning a biobank referred to in this act are made by the owner of the biobank, who is also responsible for fulfilling the obligations set for the biobank. The owner of a biobank shall appoint a custodian for the biobank.

Section 8

Duties of the custodian of a biobank

The custodian of a biobank must attend to the following:

1) performing quality control for the samples being stored;

2) maintaining, linking and protecting registers and databases;

3) ensuring the protection of privacy when processing samples and information related to them;

4) safeguarding the code key and supervising its use;

5) realising the right of access to information;

6) other duties of custodians provided in this act.

The custodian of a biobank must possess the scientific qualifications and practical experience required by the task.

Prior to accepting the position, the custodian of a biobank must sign a written assurance concerning the acceptance and performance of the duties involved.

More detailed provisions on the content of the assurance may be issued by decree of the Ministry of Social Affairs and Health.

Section 9

A biobank's notification obligation

A biobank must issue a notification to the National Supervisory Authority for Welfare and Health for the purposes of the national biobank register prior to beginning operations. The notification must contain the information referred to in section 6(2) and other information necessary to assess the legality of the operations. The notification for establishing a biobank must contain the following:

1) articles of association and extract from the trade register for the biobank or other comparable documentation if the biobank is a company or a corresponding community;

2) a statement by the National Committee on Medical Research Ethics;

3) information on the custodian of the biobank, assurance given by the custodian and information on the custodian's education and experience;

4) account of the quality system;

5) account of risk management;

6) organisation chart, number of personnel, qualifications and responsibilities;

7) register descriptions of the personal data registers maintained by the biobank;

8) a list of instructions concerning the activities.

Any changes in the information provided to the national biobank register must be reported by the biobank to the National Supervisory Authority for Welfare and Health. If the notification concerns a biobank's custodian, the notification must contain an assurance given by the custodian and information on the custodian's education and experience. If a statement by the National Committee on Medical Research Ethics has been requested on the change, it must be attached to the notification. Launching the activities of a biobank or implementing a change in the activities is possible only if the relevant information has been included in the biobank register.

More detailed provisions on submitting the notification referred to in subsections 1 and 2 may be issued by decree of the Ministry of Social Affairs and Health.

Section 10

Merging the functions of biobanks

A biobank may delegate, either partially or fully, the performance of the rights and duties laid down in this act to another biobank.

A biobank or any part of it may be merged with another biobank provided that such an action is justified considering the research area of the biobanks.

The performance or merging of functions referred to above in subsections 1 and 2 must be agreed to in writing and a notification must be submitted to the Supervisory Authority for Welfare and Health.

Chapter 3

Processing of samples and personal information associated with the samples

Criteria for processing

Section 11

Consent

A biobank's right to process samples is based on consent, unless otherwise provided in this act or in another act.

A person may issue consent for the storing of the samples taken or soon to be taken from him or her in a biobank and their use in biobank research, the provision of his or her personal information, the linking of register data concerning him or her and other processing of the samples and information obtained from him or her in connection with the samples to the extent required by biobank research. The consent shall be given in writing.

For underage persons, the consent is signed by the person who has custody of the child. If an adult does not, due to illness, lowered mental capacity or for some other reason, possess the capacity to assess the significance of the consent, a family member or someone else close to him or her may provide consent on his or her behalf. The consent must be in accordance with the presumed will of the underage or mentally incompetent person. If an underage person, when taking into account his or her age and level of development, is capable of understanding the significance and nature of biobank research, then written consent by the person him or herself is also required.

Prior to the giving of consent, the person providing consent must be provided with sufficient clarification of the nature of biobank research, any possible drawbacks, the objective of collecting and storing samples, the owner of the samples and the biobank storing the samples, the voluntary nature of the consent and the opportunity to impose restrictions on or cancel consent without negative consequences. The account must be clear and understandable. A clarification provided to an underage person or a mentally incompetent person must correspond to their capacity for understanding. The clarification must be provided in an appropriate manner and, further, always in writing.

Provisions concerning the content, signing and retaining of the consent document referred to in subsection 2 may be issued by government decree. Provisions on obligations related to the archiving of documents are laid down in the Archives Act (831/1994).

Section 12

Cancellation or change of consent

A person has a right to, at any point, cancel the consent referred to in section 11, change it or prohibit the use of a sample referred to in section 13 for research purposes or impose restrictions for its use when the sample is being stored in a biobank furnished with an identifier. In the event of a

cancellation or change of consent or a prohibition of use, a notification must be made to the custodian of the biobank. The notification shall be submitted in writing.

Once the notification of a cancellation of consent or a prohibition concerning the use of a sample has been received by the biobank, access to the sample or any information associated with the sample may no longer be granted and the sample may no longer be used for the purposes of biobank research. When the notification concerns a change of consent or imposing restrictions on use, the sample or information may only be used or otherwise processed as stipulated in the consent. If use according to the altered consent is not possible, the sample and any information associated with it may no longer be used and access to them may no longer be granted for the purposes of biobank research.

Research results produced based on the sample and information associated with it prior to the reception of the notification referred to in subsection 1, the information contained within these results and the materials formed from the sample and information may be used within the restrictions laid down in this act.

The custodian of a biobank must, upon request, issue a certificate of having received the notification referred to in subsection 1 and an account of the measures taken as a result of the cancellation of consent or prohibition on the use of the sample. No fee may be charged for the reception of the notification or measures resulting from it.

Section 13

Special provisions concerning the processing of old samples

A health care unit that, at the time of this act's entry into force, stores biological samples generated in connection with the examination and treatment of a patient (*diagnostic samples*) and patient documents associated with such samples may transfer the samples and information associated with the samples to a biobank, secrecy provisions notwithstanding. The transfer must not jeopardise the provision and implementation of patient care.

Secrecy provisions notwithstanding, an institute of higher education, a research institute, a health care unit or some other unit may transfer the samples collected and analysed in connection with a study initiated prior to this act's entry into force and the information related to them to a biobank.

A statement issued by a regional ethics committee, referred to in section 16 of the Medical Research Act, on the use of samples for biobank research is a prerequisite for the transfer referred to above in subsections 1 and 2. The statement shall be issued by the committee for the region where the samples are located. The transfer may not be performed if the person qualified to give consent prohibits the transfer of samples or information or there is reason to assume that the person, were he or she alive, would object to the use of the samples for research purposes or if the ethics committee does not consider the transfer of the samples to a biobank acceptable from an ethical standpoint. If the ethics committee does not consider the transfer of the samples to a biobank to be ethically acceptable, the National Supervisory Authority for Welfare and Health shall, upon application, issue a decision on the matter. Before the transfer, the registered individual shall be notified of a change of purpose as concerns the samples and information associated with them. The notification must state that the samples and information may be used for biobank research in case their use is not prohibited. A description of the nature of biobank research and instructions for providing consent and executing the right to prohibit use, as well as information on the biobank storing the

samples, the processing done by the ethics committee and the time of the transfer and contact information of the person receiving requests for further information must be attached to the notification.

If, due to the age or large number of the samples, or for some other similar reason, obtaining the contact information of a registered individual is not possible through reasonable effort, the notification referred to in subsection 3 must be published in an official paper, in a public communication network and, as necessary, in one or more daily papers. The National Supervisory Authority for Welfare and Health will determine, upon application, whether or not the conditions provided in this subsection are satisfied. The party holding the samples is responsible for publishing the notification.

More detailed provisions on the notification referred to in this subsection may be issued by decree of the Ministry of Social Affairs and Health.

Section 14

Information associated with a sample

When collecting or transferring samples to a biobank, information concerning a registered individual or his or her health, and information obtained from a registered individual on factors affecting his or her health may be attached to the sample, provided that the consent referred to in section 11 has been obtained for this from the person in question. As concerns old samples, the provisions in section 13 also apply.

Section 15

Transfer of samples to a biobank

If the samples have been collected based on the consent referred to in section 11, the party that collected the samples and the associated information has an obligation to transfer the samples and information to the biobank prior to their use for research purposes. If the samples have been collected as part of an individual study, however, information associated with the samples may be transferred to a biobank once the study is concluded.

If the situation in question concerns the transfer of old samples referred to in section 13, the party transferring the samples must provide the biobank receiving the samples with information regarding the statement by a regional ethics committee, referred to in section 13(3), and on the content and publication of the notification. The biobank transferring the samples and the biobank receiving the samples must conclude a written agreement regarding the transfer of the samples.

General requirements for processing

Section 16

Duty of due diligence

In addition to the provisions in sections 5 and 6 of the Personal Data Act, when processing samples with identifiers and the information associated with them, it is necessary to make sure that:

1) the sample and information associated with it are furnished with a code issued by the biobank for the purposes of retaining, storing, analysing, studying and using the sample and information;

2) the samples and information associated with them are stored separately from the code key;

3) information systems ensure the safe storage, use and monitoring of samples and personal information stored in a biobank and the verification of individual identification events.

Section 17

Protection of information

In addition to the provisions in section 32 of the Personal Data Act, the storing of samples and the implementation of information systems are arranged so that:

1) the availability and usability of information concerning criteria for the processing of samples and information is secured;

2) information concerning consent and other criteria and conditions for the use of samples shall remain intact and unchanged for the entire duration of their storage.

Provisions in the Act on the Openness of Government Activities regarding good practice with respect to information management are also applied to biobanks that do not constitute government authorities.

Section 18

Conditions for the processing of samples and information

A sample stored in a biobank and information obtained based on a sample or associated with a sample may be analysed, studied and used or otherwise processed if the processing is in accordance with the research area of the biobank and the criteria for the use of the sample and if it satisfies the conditions laid down in this act or elsewhere in law.

Section 19

Prohibitions and restrictions concerning the processing of samples

Notwithstanding the provisions laid down elsewhere in law on the right of authorities to receive secret information, access to the samples stored in a biobank and the information associated with such samples may not be granted and they may not be used for the purpose of a criminal investigation or in administrative or other decision-making concerning the person. Samples and information stored in a biobank may not be used to assess or determine the work ability of an individual or for the decision-making of credit or insurance institutions.

Registers maintained by a biobank

Section 20

The right to maintain a register

A biobank has the right to maintain personal data registers for the purposes of biobank research as provided below.

Section 21

Sample and information register

A sample and information register is a register maintained, by means of electronic data processing, for the purpose of enabling the maintenance of samples and information associated with them, as well as the surveillance and evaluation of related activities.

A sample and information register is used to store the following:

1) general information on the samples stored in a biobank to be used for research purposes;

2) information obtained through analysing the samples stored in a biobank or other information associated with the samples and obtained through other means;

3) information necessary for biobank research on the person from whom the sample was taken.

More detailed provisions on the content of the sample and information register and the technical implementation of the register to ensure the interoperability of information systems may be issued by decree of the Ministry of Social Affairs and Health.

Section 22

Consent register

A consent register is a personal data register established for the purposes of administering the criteria for the use of samples and for ensuring the realisation of self-determination with the help of electronic data processing. A consent register can be linked to a sample and information register using a code register.

Information on the following topics is collected and stored in a consent register:

1) the content and scope of consent, the time at which consent was provided, the clarification referred to in section 11(4) and the notification referred to in section 13(3);

2) cancellation and change of consent and the date and manner of its receipt;

3) prohibiting or imposing restrictions on the use of or granting access to a sample or information, and the time at which notification was provided or received;

4) criteria and conditions for the use of a sample, unless the use is based on consent referred to in section 11;

5) the unit or party that transferred the sample and the conditions for the use of the transferred samples.

Section 23

Code register

A code register is a register of personal data maintained for the purpose of ensuring the protection of privacy. The code register makes it possible to link data in the sample and information register to information in the consent register with the help of electronic data processing.

Information on the following topics is collected and stored in the code register:

1) name and personal identity code of the individual;

2) code key.

If the consent is cancelled, or if the use of the sample is terminated for other reasons, information concerning the sample must be removed from the code register.

Section 24

Right of access to information in the sample and information register

An institution, company, community or individual performing biobank research has the right of access to information referred to in section 21(2)(1) in the sample and information register that is necessary for assessing the usability of the samples and information stored in the biobank and that does not contain information referred to in section 11 of the Personal Data Act.

Section 25

Removal and transfer of samples and register data

The need to store samples and information associated with them must be assessed on a regular basis, at least every ten years. Samples and information that are not necessary with respect to the biobank's area of research and criteria for processing the sample shall be destroyed.

If the ownership and control of a sample and the information associated with it are transferred to another biobank, or if the sample is destroyed, information concerning the sample contained in the registers referred to in sections 21 to 23 shall be removed. The transferred samples shall be recoded by the biobank receiving them.

If the operations of a biobank are terminated, the samples and information associated with them shall be destroyed and the consent register and the sample and information register shall be transferred to an archive, as provided in the Personal Data Act, unless the samples and information associated with them are transferred to another biobank. Upon the termination of operations of a biobank, the custodian of the biobank shall destroy the code register.

Use of samples and information in biobank research

Section 26

Principles for granting access to samples and information

A biobank may grant access to, study or otherwise process the samples and information stored by it provided that:

1) the intended use corresponds to the research area defined for the biobank and the criteria and conditions established for the processing of the sample;

2) terms and restrictions provided in this act or elsewhere in law and determined by the biobank are observed in the research and in the processing of samples and information;

3) the individual granted access to the samples or information holds the appropriate professional and academic qualifications for processing the samples and information, and the granting of access to the sample or information is in connection with the duties of the recipient.

The samples and information associated with them shall be coded prior to granting access to them for research purposes, unless there is specific reason for not doing so.

The codes used in connection with the granting of access are formed on a project-by-project basis as access is granted. The codes used in the storing of samples and information may not be given out by the biobank. Access to personal data may only be granted based on consent from the registered individual or some other person qualified to provide consent in the event that no other criteria is provided in this act for granting access to the information.

Section 27

Granting access to samples and information

A person requesting access to the samples or information stored in a biobank must attach the following documents to a written request addressed to the biobank: a research plan, a statement by a competent ethics committee referred to in the Medical Research Act or other statement necessary to assess the fulfilment of the conditions for granting access to the samples and information and an account of the processing of the samples and information.

A biobank may restrict the granting of access to samples and information only if it is justified when considering the following:

1) the biobank's research area and other restrictions concerning the granting of access to the samples and information associated with them referred to in section 6(2)(4).

2) securing intellectual property rights related to research, the realisation of research projects referred to in section 15 or ensuring the preservation of samples or the collection of samples;

3) ensuring data protection; or

4) reasons pertaining to research ethics.

A written agreement must be drawn up regarding the granting of access and the terms related to it. An obligation to publish the results of biobank research based on the samples or information received from the biobank must be established for those granted access to samples or information. The provisions in Section 28 of the Act on the Openness of Government Activities on the right of an authority to grant access to secret documents in individual cases are also applied to biobanks that do not constitute government authorities.

The provisions in this section on procedures and restrictions to be observed in the granting of access to samples and information shall also be applied in the biobanks' own research projects.

Section 28

The granting of access to personal data for the purpose of linking register data

The biobank may provide necessary personal data to the National Institute for Health and Welfare or to another registrar provided that linking the details in the personal data registers maintained by the registrar to the samples or information stored by the biobank is justified for the purpose of implementing research and that granting access to the information satisfies the conditions laid down in section 26(1).

The National Institute for Health and Welfare or another registrar must furnish the register data they have linked to the personal data using the project-specific codes obtained from the biobank prior to releasing it to the individual responsible for the study in question, unless specific consent for granting access to the personal data has been obtained from the registered individual or another person qualified to provide consent.

Section 29

Obligations of a party granted access to samples or information

The party granted access to a sample or information may store and use the samples obtained from a biobank and the information associated with them for the duration of the research cited in the research plan referred to in section 27, unless a longer period has been agreed upon in the agreement referred to in section 27(3). If, based on the agreement, the party granted access to samples or information has the right to store the samples for future research, the provisions contained in this act regarding the conditions for the processing of samples will be applied.

A person who has received samples with identifiers and information from a biobank may grant access to the samples and information received within the restrictions laid down in this act, provided that the right of access to information is based on law.

Chapter 4

National biobank register

Section 30

National biobank register and its objective

The National Biobank Register has been established for the dissemination of information on biobank research, for the provision of information to citizens and researchers, and for the supervision of activities in the field. The register is maintained by the National Supervisory Authority for Welfare and Health.

The register contains information on biobanks established in Finland, including information on the owners and custodians of such biobanks. In addition, the register has general information on the number of samples stored in biobanks, the research areas of biobanks, the conditions for obtaining

samples and other factors related to the usability of the samples and the information associated with them as well as any information on possible decisions taken by authorities.

More detailed provisions on the information content of the register may be given by decree of the Ministry of Social Affairs and Health.

Chapter 5

Supervision and coercive measures

Section 31

Guidance, supervision and monitoring

The guidance and supervision of the activities provided for in this act is the duty of the National Supervisory Authority for Welfare and Health.

The National Institute for Welfare and Health and the Finnish Medicines Agency will function as the expert authorities and institutes for biobanking activities in their respective sectors.

In addition, provisions on the duties of the Data Protection Ombudsman are laid down in the Act on the Data Protection Board and the Data Protection Ombudsman (389/1994).

Section 32

An authority's right to inspect and receive information

To supervise compliance with this act and the provisions issued under it, the National Supervisory Authority for Welfare and Health has the right to inspect the facilities, operations and necessary documentation of a biobank.

The inspector, appointed by the National Supervisory Authority for Welfare and Health, must have access to all premises of the biobank and, secrecy provisions notwithstanding, must be presented with all documents requested by him or her that are necessary to perform the inspection. The inspection may not, however, be carried out in facilities used for permanent habitation. The inspector must be provided with the copies of documents requested by him or her necessary for performing the inspection free of charge. The inspector has the right to take photographs during the inspection.

The National Supervisory Authority for Welfare and Health must issue a copy of a record of the inspection within 30 days of the inspection for the information of the owner and custodian of the biobank. The inspection is deemed completed once a copy of the inspection record has been issued to the parties.

The custodian of the biobank must launch measures to remedy the deficiencies identified in the inspection without delay. The custodian must notify the National Supervisory Authority for Welfare and Health of any measures to be launched, as well as the schedule and details of their implementation, within 30 days of the date of receiving the inspection report.

The National Supervisory Authority for Welfare and Health has the right to receive, free of charge and secrecy provisions notwithstanding, the necessary information from a biobank, a local or

central government authority, other public corporation, a community or institution practising health care or medical care, or a body or individual engaging in biobank research.

Section 33

Orders and coercive measures

If, in connection with an inspection or otherwise, deficiencies concerning information security or the protection of personal data are detected in the operations of a biobank or in the processing of samples, or if the biobank does not otherwise fulfil the obligations provided in this Act, the National Supervisory Authority for Welfare and Health may:

1) issue an order on the remedying of deficiencies or elimination of grievances;

2) oblige the biobank to provide samples or information associated with the samples stored by it;

3) prohibit the processing of samples stored in the biobank or impose restrictions for it.

The decision referred to above in subsection 1 must contain a deadline by which all the necessary measures must be completed in case information concerning the biobank and its activities is to remain in the national biobank register. The appointed time may not be shorter than 60 days.

If the deficiency detected in the activities of a biobank is likely to jeopardise the privacy or rights of the person from whom the sample was taken, the National Supervisory Authority for Welfare and Health may temporarily remove information concerning the operations of the biobank from the national biobank register or prohibit the processing of samples until the final resolution of the matter.

The National Supervisory Authority for Welfare and Health may remove information concerning the operations of a biobank from the national biobank register in the event that serious deficiencies related to the protection of personal data or information security are detected in the operations of the biobank or in the processing of samples or associated information or that the biobank is repeatedly guilty of procedures in violation of the provisions, and the measures cited in the decision referred to in subsection 1 have not led to the fulfilment of obligations. The operations of a biobank are terminated if the National Supervisory Authority for Welfare and Health removes the biobank from the national biobank register. At the same time, the National Supervisory Authority for Welfare and Health decides on the transfer or destruction of samples and information associated with them.

Section 34

Processing of notifications

The National Supervisory Authority for Welfare and Health must process notifications submitted to the national biobank register as quickly as possible. The National Supervisory Authority for Welfare and Health may request additional clarification if necessary.

The National Supervisory Authority for Welfare and Health shall enter information concerning a biobank into the national biobank register provided that the statement issued by the National Committee on Medical Research Ethics referred to in section 6 is positive and the operations described in the notification satisfy the conditions laid down for it in this act and elsewhere in law.

In the event that there is no obstacle to including the information in the register, the information provided must be in the register within 60 days of the receipt of the notification by the National Supervisory Authority for Welfare and Health. The period for obtaining additional information or reports is not included in the period of issue.

Section 35

Transfer of biobanking operations to another country

In the event a biobank intends, either fully or partially, to shift its operations outside of Finland, it must apply for permission from the National Supervisory Authority for Welfare and Health. Granting a research institute access to samples and information for the purpose of conducting necessary analyses does not count as a transfer of biobanking operations. An account of how the rights of individuals from whom the samples have been taken will be secured during the transfer and once the transfer has been completed must be attached to the application. A statement by the owner of the samples must be attached to the application, provided that the transfer concerns samples other than those owned by the biobank.

The permission may not be granted in the event that the transfer of samples and information prevents the realisation of the rights provided in this act or elsewhere in law to ensure the protection of privacy or self-determination. The National Supervisory Authority for Welfare and Health must issue a decision within 60 days of receiving the application. The period for obtaining additional information or reports is not included in the period of issue.

The National Supervisory Authority for Welfare and Health may issue more specific orders on the procedures to be followed when applying for the permission.

Section 36

Notification duty of health care units

Health care units must, without delay, provide the National Supervisory Authority for Welfare and Health with information on diagnostic samples and the information associated with them transferred to a biobank. Health care units must attach to the notification a copy of an agreement concerning the transfer and documents referred to in section 15(2).

Health care units must maintain a listing of prohibitions on the use of diagnostic samples for biobank research referred to in section 13(3). Health care units and biobanks may use the listing to ensure the realisation of the right to prohibit the use of the samples for research purposes.

Upon request, health care units must provide an account of whether the diagnostic samples taken from the person requesting the information have been transferred to a biobank under section 13. If the transfer has been made, the person shall be provided with information on the biobank that has received the sample.

The National Supervisory Authority for Welfare and Heath may issue more detailed provisions on preparing the notification referred to in subsection 1.

Section 37

Implementation

A decision by the National Supervisory Authority for Welfare and Health may be implemented regardless of an appeal, provided that the appellate authority does not forbid the implementation of the decision, order a discontinuation of the implementation or order otherwise in another order concerning the implementation.

Section 38

Executive assistance

Provisions on the obligation of the police to give executive assistance are laid down in section 40 of the Police Act (493/1995).

Chapter 6

Miscellaneous provisions

Section 39

Right of access of registered individuals

Everyone has the right to receive, upon request, information on whether or not samples concerning them are being stored in a biobank included in the biobank register, on the criteria based upon which the samples are stored, on the source of information concerning them and on the recipients of samples taken from them and associated information as concerns granting access to the samples and information and transferring them from the biobank. The right of access may also be realised through an online viewing connection. It is acceptable to charge a fee for the provision of the information that, at maximum, corresponds to the costs incurred by providing the information.

A registered individual has the right to receive, upon request, information concerning his or her health as determined based on a sample. When providing information determined based on the sample, the person must be provided with an opportunity to receive an account of the significance of the information. A fee may be charged for clarifying the significance of the information that, at maximum, corresponds to the expenses incurred by providing the clarification.

The request for information must be made in writing to the biobank.

Section 40

Non-disclosure and secrecy

Sections 22 to 24 and section 35 of the Act on the Openness of Government Activities are applied to the secrecy of documents obtained or drawn up when performing the tasks provided for in this act or related to the implementation of this act and the information contained within the documents and also to the duty of non-disclosure and prohibition of use concerning information obtained while performing these tasks in situations that do not concern documents issued by an authority referred to in the act in question.

The secrecy obligation does not prevent a person from providing information on consent concerning the use of the sample, on cancellation or change of consent, or on a prohibition concerning the use of the sample to the party that has received the samples or information associated with them through a transfer or by having been granted access to them.

Section 41

Fees

Fees are charged for an initial notification made in the national biobank register and for a notification of change in register information, granting access to information in the national biobank register and maintaining the national biobank register as provided in the Act on Criteria for Charges Payable to the State (150/1992) and in section 34 of the Act on the Openness of Government Activities.

Separate provisions shall be issued regarding charges payable for statements by the National Committee on Medical Research Ethics and regional ethics committees and for decisions and statements and the processing of matters by the Supervisory Authority for Health and Welfare as well as regarding service charges other than those referred to in subsection 1.

No payment shall be made or promised to the donor of a sample or to his or her assignee for providing samples to a biobank.

Section 42

Appeals

Decisions issued by the Supervisory Authority for Welfare and Health and biobanks under this act shall be appealed as provided in the Administrative Judicial Procedure Act (586/1996).

Statements issued by the National Committee on Medical Research Ethics or the regional ethics committee referred to in this act may not be appealed.

A fee ordered by a government authority may be appealed as provided in section 11b of the Act on Criteria for Charges Payable to the State.

Section 43

Penal provisions

Any person who intentionally or out of gross negligence

1) processes samples in a manner that is in violation of the provisions in Chapters 2 and 3 and neglects the notification duty provided in section 9,

2) violates a prohibition or order issued by a supervisory authority under 33(1),

3) provides information concerning a code key or an individual to an unauthorised party or

4) grants access to or transfers a sample or information associated with it in a manner that is in violation of this act,

thus compromising the protection of privacy of the donor and his or her rights, shall be sentenced to a fine for *a violation of provisions concerning biobanks*, unless a more severe penalty is provided elsewhere in law.

The penalty for a computer break-in is provided in section 8, Chapter 38 of the Criminal Code (39/1889), for a personal data offence in section 9, Chapter 38 of the Criminal Code and for a personal data violation in section 48 of the Personal Data Act. The penalty for violation of a secrecy duty is provided in sections 1 or 2 of Chapter 38 of the Criminal Code, unless the act is punishable under section 5, Chapter 40 of the Criminal Code or a more severe penalty is provided in another Act.

Chapter 7

Transitional provisions and entry into force

Section 44

Entry into force

This Act enters into force on 1 September 2013.

Once this act has entered into force, decisions concerning the transfer of collections of samples suitable for biobank research to a biobank and the schedules for such transfers shall be decided by the Ministry of Social Affairs and Health. Procedures laid down in section 13 are applied regarding the transfer of the samples.

A joint municipal authority maintaining a university hospital, together with the joint municipal authorities of hospital districts and the municipalities and joint municipal authorities maintaining health care units within a specific catchment area, may establish a regional biobank as agreed upon in the health care provision plan referred to in section 34 of the Health Care Act (1326/2010) and in the agreement on the provision of specialised medical care referred to in section 43 or otherwise.

Measures necessitated by the implementation of the Act may be launched prior to the Act's entry into force.