Biobank Sweden's translation of the Biobank Act (2023:38)

An unofficial translation

Biobank Act (2023:38)

Ministry: Ministry of Health and Social Affairs

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Chapter 1 General provisions

Content of the Act

Section 1
This law contains provisions on how human biological material may be collected for certain purposes and preserved in a biobank and used, with respect for the i integrity of the individual sample donor.

Terms and definitions used in the law

Section 2
In this law the following expressions are used.

Expression	Meaning
Anonymization	Action taken to ensure that the origin of a sample is neither directly nor indirectly traceable to the person or foetus from whom it was taken.
Biobank	One or more sample collections held by one and the same principal.
Principal of a biobank	Legal entity responsible for a biobank.
Healthcare	Activities covered by the Health and Medical Services Act (2017:30) or the National Dental Service Act (1985:125).
Identifiable sample	Sample whose origin can be directly or

	indirectly traced to the human or the foetus from which the sample has been taken from.
Sample	Biological material from a living or deceased person or from a foetus.
Sample donor	1. Living person from whom a sample has been taken, or 2. living person who carries or has carried a foetus from which a sample has been taken.
Sample collection	One or more samples kept for a specific purpose in a biobank.
Healthcare providers	Any organisation who according to the Health and Medical Services Act or the National Dental Service Act is a healthcare provider.

Scope of the Act

Section 3

The Act applies to identifiable samples collected and stored in a biobank or used for

1. care, treatment, or other medical purposes within the provision of healthcare,
2. research,
3. product manufacturing, or
4. education, quality assurance or development work within the framework of any of the purposes stated in 1-3.

Section 4

The law will only be applied to a sample which is stored for more than nine months after the time of its collection. However, the law must be applied to the sample if

1. the intention from the outset is to store the sample for more than nine months, or
2. the sample is not destroyed immediately after it has been analysed.

Exemptions to the scope of the act

Section 5

The law does not apply to

1. a sample collected, stored or used for transfusion, transplantation, insemination, or fertilization outside the body,
2. a sample collected, stored or used to form part of a drug or medical device, or
3. a sample that, in the case of transfusion or transplantation, is kept only for quality assurance.

If the purpose, after a sample has been collected, changes to something other than the purposes stated in the first paragraph, the exemptions in the first paragraph no longer apply.

Section 5a
The Act shall also not apply to human biological material covered by the Act (2023:281) on the National Board of Forensic Medicine's handling of human biological material.

Law (2023:285).

Section 6
The law will also not be applied to a sample which has been significantly modified within the framework of research or product manufacturing if

1. the sample donor has received information that the sample will be significantly modified and that it will then no longer be covered by this Act, and
2. the sample donor has consented to such a modification according to the provisions in Chapter 4.

The relationship to other data protection regulations
Section 7
This law complements Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free flow of such data and on the repeal of Directive 95/46/EC (General Data Protection Regulation), here referred to as the EU Data Protection Regulation.

When processing personal data in accordance with this Act, provisions in other Acts on the processing of personal data and the Act (2018:218) with supplementary provisions to the EU's data protection regulation and regulations which have been issued in connection with that Act apply, unless otherwise stated by this Act or regulations which have been issued in connection with this Act.

Duty of professional secrecy in qualified cases
Section 8
Anyone who is or has been employed or contracted in an private business with an established biobank may not authorize the disclosure or use information in

1. an application for permission for a clinical drug trial,
2. an application or notification for a clinical trial according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, or
3. an application or notification of a performance study according to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices for in vitro diagnostics and on the repeal of Directive 98/79/EC and Commission Decision 2010/227/EU.

A disclosure is not considered unauthorised if it is made under the obligation of another act or regulation within Swedish law.

Chapter 2 Obligations arising from the establishment of biobanks and sample collections

Establishment and division of responsibilities

Section 1

A biobank can only be established by a legal entity, which then by definition becomes the legal principal. The legal principal must then assign responsibility for the biobank to a qualified person and also define the purpose or purposes for which the biobank may be used.

Section 2

It is the person responsible for a biobank who decides whether a new sample collection will be established and for which purpose or purposes it will be used.

Section 3

The principal of a biobank is responsible for ensuring that adequate resources are available for maintaining and operating the biobank in accordance with the requirements of this law. The legal principal is also responsible for the handling of personal data necessary for maintaining and operating the biobank according to this law.

Section 4

The person responsible for the biobank is also responsible for its operation being conducted in accordance with the requirements of this law.

Permitted purposes

Section 5

Samples may be collected and stored in a biobank only for the purposes specified in Chapter 1, Section 3.

A sample from a biobank may only be used

1. for the purposes of Chapter 1, Section 3, or
2. to investigate injuries according to the Patient Injury Act (1996:799).

A sample from a biobank may also, under the conditions specified in Chapter 5, Section 11, first paragraph, be used to identify persons who are deceased.

Section 6

Samples may be collected, stored and used for purposes relating to research, which is not covered by the provision on clinical trial of medicinal products for human use in section 7, only after review and approval by the Ethics Review Authority or the Board of Appeal for ethics review. A sample may be used for research other than that which has been reviewed and approved only if the authority or committee approves this.

In the case of such review and approval the provisions of the Act on Ethical Review (2003:460) Sections 7-11 will apply, as well as the provisions on handling and appeals in Sections 24-33, 36 and 37 in that Act.

Section 7

Samples may be collected, stored and used for the purpose of a clinical trial of medicinal products for human use only after an application for permission for clinical drug trial has been granted or will be deemed to have been

granted in accordance with Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of human medicinal products and on the repeal of Directive 2001/20/EC. However, this only applies if the application for permission contains information on the collection, storage, and use of biological samples.

Registration

Section 8
The principal of a biobank is responsible for registering any decision to establish a biobank to the Health and Social Care Inspectorate

Such registration must contain information about

1. the purpose of the biobank,
2. who is the principal of the biobank,
3. who is responsible for the biobank, and
4. the intended scale of the biobank.

Registration must be made no later than one month after the decision to establish the biobank. If any circumstances change for a biobank already registered, these must also be reported to the Health and Social Care Inspectorate within one month of the changes taking effect.

Storage

Section 9
Samples in a biobank must be stored safely to avoid risks of being destructed. Unauthorized access must be prevented.

Section 10
If decisions are taken to remove samples from a biobank, for instance due to consent withdrawal or other legal provisions, the person responsible for the biobank must ensure that such samples are destroyed or anonymized.

Chapter 3 Register of biobanks

Section 1
The Health and Social Care Inspectorate must keep an updated registry of all biobanks. The registry shall be used for governance, research and the generation of statistics. The registry must contain the obligatory information reported to the Health and Social Care Inspectorate according to Chapter 2, Section 8. It may not contain information about individuals from whom samples were taken.

The Health and Social Care Inspectorate is the personal data controller for the registry.

Chapter 4 Consent and information

General provisions

Section 1
In order for a sample to be collected and stored in a biobank, the sample donor must have consented to it, unless otherwise exempted in this chapter or other law. Consent to storage shall also include consent to use unless

otherwise expressly stated.

Section 2
Prior to consent given for a sample to be collected and stored in a biobank, the sample donor must have received information on

1. the purpose of collection and storage of the sample,
2. the purpose of the sample collection and what the sample may be used for,
3. what purposes are permitted under this Act, and
4. their right to withdraw or limit their consent.

Section 3
The Ethical Review Act (2003:460) for research involving humans, includes provisions on information and consent which must be applied. If there are special provisions on information and consent in another law, then these must also be applied.

However, this does not apply for samples collected, stored or used in accordance with Section 5 or 9.

When the sample donor is a child

Section 4
If the sample donor is a child, information must be given to the child's custodial parent unless the child has reached such an age and maturity that the child can judge the matter to which the information applies. It is also the custodial parent who can grant consent or object to collection, storage or use of a sample in these cases.

Section 5
A sample from a child who has not reached such an age and maturity that they can make a decision on donating their sample to a biobank may be collected and stored even if the child's custodial parent does not consent to this, if there is a significant risk of the child's health being harmed without the sample being taken.

Such decisions as described in this section must be made by the principal of the biobank.

Section 6
In the case of samples taken and stored from a child who was not able to make a decision on the sample donation and without the custodial parent's consent, when the sample donor turns 18, the principal of the biobank is responsible for informing the sample donor as follows:

1. that the sample is stored in the biobank and that this was done without the custodial parent's consent,
2. what the sample may be used for,
3. that the sample donor can now decide what the sample can be used for in the future, and
4. that the sample donor can decide to have the sample destroyed or anonymized.

If the principal of the biobank becomes aware that the sample donor has reached such an age and maturity that they can make a decision on the processing of the sample themselves before turning 18, the information described in this section must then be provided at this time.

Care or treatment

Section 7

Consent under this Act to collect, store and use a sample for the care or treatment of the donor of the sample is not required if the sample donor has

1. consented to care or treatment according to the Patient Act (2014:821) or the Dental Care Service Act (1985:125), and
2. received information about
    a. the intention to collect and store the sample,
    b. the purpose of the sample collection and what the sample may be used for,
    c. what purposes are permitted under this Act, and
    d. their right to withdraw or limit a consent to collect, store or use their sample in a biobank.

A sample referred to in this section may also be stored for the future purposes of:

1. the quality assurance and development work of healthcare activities,
2. education conducted in connection with healthcare, or
3. research.

The first and second points here apply on condition that the sample donor has not made any active objections to such collection, storage or use.

Section 8

A sample may be collected for and stored in a biobank for the sample donor's care or treatment, even if the sample donor, due to illness, mental disorder, or has a weakened state of health or any other similar condition, cannot make an active judgement on donating their sample for biobanking.

Section 9

A sample collected according to section 5 or 8 can only be stored for the sample donor's care or treatment or for quality assurance and development work of healthcare activities.

New purpose

Section 10

A sample stored in a biobank may be used for a purpose other than that covered by previous information and consent only if the person who provided the consent has been informed of and consented for the new purpose.

A sample which, according to Section 7, is stored for the care or treatment of the sample donor may also be used for quality assurance and development work of healthcare activities and for education conducted in connection with healthcare, if the sample donor has not objected to such use.

If the person who has given consent has passed away, the sample may be used for a different purpose than the consent intended only if the next of kin to the deceased have been informed of, and after a reasonable time for consideration, not objected to the new purpose.

Section 11

If the new purpose relates to research which is not covered by the provision in Section 12 on clinical trials of medicinal products for human use, the

Ethics Review Authority or the Board of Appeal for ethics review must, together with the authority or the board approving the new purpose, also decide which requirements will apply for information and consent for the new purpose.

Section 12
If the new purpose is a clinical trial of medicinal products for human use, the samples may be used for such a trial in accordance with the application for a clinical trial of medicinal products for human use authorization which has been granted or deemed to have been granted in accordance with Regulation (EU) No. 536/2014. However, this only applies if the application for permission contains information on the collection, storage, and use of biological samples.

Revocation and limitation of consent

Section 13
A consent for storing or using a sample may be withdrawn by the donor at any time. If the withdrawal concerns consent to the storage of the sample or to any use thereof, the person responsible for the biobank is obliged to immediately destroy the sample. If it is not possible to destroy the sample without destroying other samples, the person responsible for the biobank is obliged to anonymize the sample immediately.

Section 14
The donor of the sample or the person who has consented to the use of a sample may at any time instruct that a sample may not be used for one or more of the purposes permitted under this Act. Such notification must be documented in the sample donor's patient record or in a registry kept in the biobank concerned.

Exemption to the requirement of consent

Section 15
Consent is not required for a sample in a biobank that has been collected and stored for care or treatment to be used to identify a deceased person.

Chapter 5: Making samples and data available

General provisions

Section 1
A sample from a biobank may, under the conditions specified in this chapter, be made available by

1. being released,
2. being sent for a specific action to be performed, or
3. a formal transfer of the sample or the biobank in which the sample is stored.

A sample from a biobank may only be made available to legal entities.

Section 2
A sample from a biobank may not be made available for profit.

Coding

Section 3
A sample made available must be coded, unless this prevents the intended purpose.

Section 4
If a coded sample from a sample donor is made available at the same time as other personal data from the same sample donor, the personal data must be made available in such a manner that it cannot be connected to the sample by anyone unauthorized.

Section 5
If the patient has consented, their medical record within the relevant healthcare system must be made available to the person who has been given access to the coded sample from that patient.

Release

Section 6
A sample may only be released to a recipient in Sweden after the recipient has requested it.

A released sample ceases to be part of the biobank from which it was released. A sample which is stored after having been released must be included in a new or existing biobank in the premises of the recipient.

Sending samples for specific actions

General provisions

Section 7
A sample may be sent to a legal entity in order for a certain procedure or analysis to be carried out. The sample does not cease to be included in the biobank from which it was sent.

Section 8
When a sample is sent from a biobank for a certain procedure to be performed, the person responsible for the biobank must

1. enter an agreement with the recipient on the purpose of making it available and what is going to happen with sample after the procedure has been carried out, and
2. set as a condition for making it available that
    a. a sample preserved by the recipient shall, if requested by the principal of the biobank, be returned or immediately destroyed or, if it is not possible to destroy it without destroying other samples, anonymized, and that
    b. the recipient must not use the sample for anything other than the stated purpose.

Section 9
A sample that is to be used to investigate an injury according to the Patient Injury Act (1996:799) may only be made available in the manner specified in section 1 paragraph 2.

Additional requirements for a sample to be transferred for research

Section 10

A sample may be sent for research only if the sample is to be included in:

1. research approved by the Ethics Review Authority or the Board of Appeal for ethical review according to the Act (2003:460) on ethical review of research involving humans,
2. a clinical trial of medicinal products for human use that has been granted or deemed to have been granted permission in accordance with Regulation (EU) No 536/2014,
3. a clinical trial which may be started or carried out in accordance with provisions in regulation (EU) 2017/745 or in accordance with the law (2021:600) with supplementary provisions to the EU regulations on medical devices or regulations issued in connection with particular law, or
4. a performance study which started or carried out in accordance with the provisions of Regulation (EU) 2017/746.

Additional requirements for a sample to be sent to the National Board of Forensic Medicine or the Swedish Police Authority

Section 11

If the National Board of Forensic Medicine or the Swedish Police Authority requests it, a sample must be sent to the national board or authority for the identification of a deceased person. However, this only applies if

1. the sample was collected or stored for care or treatment, and
2. there are special reasons for the request.

When a sample is sent, the associated personal data needed must also be sent.

Transfer

Section 12

A sample collection or biobank may only be transferred to a recipient in Sweden.

In the event of a transfer, responsibility for storage and use of the samples passes to the recipient. The purpose of a collection of samples does not change when it is transferred.

The sample collection or the biobank may only be transferred if there are special reasons, and the Health and Social Care Inspectorate approves the transfer.

Review of applications for sample access

Section 13

The person responsible for a biobank must review applications for making samples available. The principal of the biobank is obliged to reconsider a decision if requested by the applicant.

The applicant must be informed of their right to request a reconsideration.

Section 14
Questions on the disclosure of a medical record according to Section 5 must be examined by the person responsible for the patient's medical records. If the person responsible considers that the medical records or any part of it should not be disclosed, they must immediately inform the Health and Social Care Inspectorate for further review.

In the case of appeals against such decisions by the Health and Social Care Inspectorate, chapter 6 sections 7-11 of the Public Access and Secrecy Act (2009:400) apply.

Chapter 6: Closure of a biobank or sample collection

Section 1
The principal of a biobank may decide that the biobank or one or more of its sample collections should be terminated.

If a biobank is closed down, the principal of the biobank must report the decision to the Health and Social Care Inspectorate. The notification must contain information about what has happened to the samples in the biobank.

Chapter 7: Biobank with samples from children

Area of application

Section 1
Government approved healthcare providers may, for the purposes specified in Section 2, collect, store or use samples from new-born children in a special biobank (PKU biobank). This also applies to samples from children who have not provided such samples as new-borns.

Permitted purposes for samples in the PKU biobank

Section 2
Samples may be collected and stored in the PKU biobank only for:

1. analyses and other investigations to trace and diagnose such diseases that are specified in regulations that have been announced pursuant to Section 8, second paragraph,
2. retrospective diagnosis of other diseases in individual children,
3. epidemiological investigations,
4. follow-up, evaluation and quality assurance of healthcare activities, or
5. clinical research and development.

A sample from a PKU biobank may only be used

1. for the purposes stated in the first paragraph, or
2. to investigate injuries according to the Patient Injury Act (1996:799).

A sample from a PKU biobank may also, under the conditions specified in Chapter 5, Section 11, first paragraph, be used to identify persons who are deceased.

Obligation to provide samples

Section 3
A healthcare provider is obliged to comply with the requirements in Chapter 4 to hand over such samples as referred to in Section 1 for analysis and to be preserved in the PKU biobank.

Registry

Section 4
Healthcare providers referred to in Section 1 may, with the help of automated processing or other processing of personal data, keep a special registry for screening samples from children for such diseases as those specified in regulations described in Section 8, second paragraph (PKU registry).

The healthcare provider is the data controller for this registry.

Section 5
The PKU registry may only be used for the purposes stated in Section 2 and to produce statistics.

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

1. mother's name, national registration number and place of residence,
2. length of pregnancy,
3. the sample donor's date of birth, birth weight, gender and national registration number and ordinal number in case of multiple births,
4. the healthcare unit which took the sample,
5. analysis and results from examination,
6. diagnosis,
7. information on treatment of diagnosed diseases,
8. information that may be important for interpretation and follow-up of the result, and
9. details of information provided to and consent from the sample donor or their custodial parent.

Section 7
A healthcare provider is obliged to provide information pursuant to Section 6 of the PKU registry when a sample has been taken from a child and the child's custodial parent has explicitly consented to taking the data transfer.

Before the custodial parent gives their consent, they must have been informed about what information is being registered and the purpose of the registration.

If the child has reached such an age and maturity that they can judge on the matter of data transfer, then the first and second paragraphs about the custodial parent applies to the child.

Authorizations

Section 8
The government may issue regulations on which criteria must be taken into account in order for a disease to be traced and diagnosed pursuant to Section 2 paragraph 1.

The government or the authority designated by the government may issue regulations on which congenital diseases the samples in the PKU biobank may be used for pursuant to Section 2 paragraph 1.

Chapter 8: Other provisions

Penal provisions

Section 1

Fines are imposed on those who intentionally or negligently

1. use a sample in contravention of Chapter 2 Section 5 second or third paragraph or Chapter 7 Section 2 second or third paragraph,
2. set up a biobank without making a notification pursuant to Chapter 2 Section 8,
3. store a sample in a biobank in violation of Chapter 2 Section 9,
4. do not provide information or obtain consent pursuant to Chapter 4 Sections 2 and 6, first paragraph or Section 10, first paragraph,
5. do not destroy or anonymize a sample pursuant to Chapter 4 Section 13,
6. make available a sample from a biobank in contravention of Chapter 5 Section 6 first paragraph or Section 8,
7. transfer a collection of samples in contravention to Chapter 5 Section 12, third paragraph, or
8. do not release a sample pursuant to Chapter 7 Section 3.

Chapter 8 Section 6 of the Act (2006:351) on genetic integrity etc. contains provisions on punishment for those who transfer biological material for profit.

Damages

Section 2

If a sample is handled in violation of this law, the principal of the biobank will compensate the sample donor for the harm and violation of personal integrity that the process has caused them.

Supervision

Section 3

The Health and Social Care Inspectorate is responsible for compliance with this law and the regulations which have been announced in connection with it. However, the supervisory authority according to the EU's data protection regulation exercises supervision over the processing of personal data.

Anyone who conducts activities which are subject to compliance with this law is obliged to hand over documents, samples and other material relating to the activity at the request of the Health and Social Care Inspectorate, as well as to provide the information about the activity that the inspection needs for exercising its responsibility.

The Health and Social Care Inspectorate may demand the person running the activity to disclose what is requested. A decision of an injunction may be combined with a fine.

Section 4
The Health and Social Care Inspectorate or a person appointed by the inspection, is entitled to inspect activities which are subject to compliance with this Act.

An inspection can be announced or unannounced. The person carrying out the inspection has the right to gain access to premises or other spaces used for the activities, however not private residences. The person carrying out the inspection has the right to temporarily dispose of documents, samples and other material relating to the activities.

The person whose work activities are inspected is obliged to provide the assistance needed during the inspection.

Section 5
The person undertaking the inspection is entitled to receive help from the police authority needed for the inspection to be carried out.

Such assistance may only be requested if

1. it is likely that, due to special circumstances, the measure cannot be carried out without police special powers pursuant to Section 10 of the Police Act (1984:387) having to be resorted to, or
2. in case of other exceptional reasons.

Section 6
If the Health and Social Care Inspectorate becomes aware that someone has breached a provision of this law, the inspectorate must take measures to ensure that the provision is followed and, if this does not yield results, a report for prosecution must be filed.

Appeal

Section 7
The following decisions may be appealed to the Health and Social Care Inspectorate:

1. decision pursuant to Chapter 4 Section 5 on collecting or storing a sample from a child without the consent of the custodial parent, and
2. decision pursuant to Chapter 5 section 11 not to send a sample to identify a deceased person.

Decisions pursuant to Chapter 5 Section 11 may only be appealed by the Swedish National Board of Forensic Medicine or the Swedish Police Authority.

A decision made by the Health and Social Care Inspectorate may according to this law be appealed to the general administrative court.

Leave to appeal is required in the event of an appeal to the Administrative Court of Appeal

Other decisions under this law may not be appealed.

Section 8
If an individual as principal of a biobank makes a decision referred to in Section 7, Sections 43-47 of the Administrative Procedure Act (2017:900) apply in the matter of appeals. The principal of the biobank must then be considered to be an authority.

Enforceability of decisions

Section 9

The Health and Social Care Inspectorate or general administrative courts decisions under this law apply immediately, unless the inspectorate or the court decides otherwise.

Authorizations

Section 10

The government or an authority designated by the government may issue regulations on

1. which authorities may have direct access to the registry of biobanks kept by the Health and Social Care Inspectorate,
2. duration of storage of samples in biobanks,
3. storage and coding of samples in biobanks,
4. the information to be provided under this law,
5. the consent to be provided by the sample donor,
6. traceability of samples in biobanks,
7. the procedure for notifications about the establishment of biobanks,
8. screening of samples in biobanks,
9. shutting down biobanks, and
10. transfer of collections of samples.

Transitional provisions

2023:38

1. This law enters into force on July 1, 2023.
2. The law also applies to samples collected prior to this date. However, no new consent is required for such samples as long as a new purpose is not intended, pursuant to Chapter 4 Section 10 first or third paragraph, Sections 11 and 12.
3. If a biobank has been established and registered with the Health and Social Care Inspectorate prior to this law coming into force, the activities relating to the biobank may continue to be conducted without a new notification to the Health and Social Care Inspectorate being made pursuant to Chapter 2 Section 8.
4. The law repeals the Act (2002:297) on biobanks in healthcare, etc.
5. However, the repealed law will continue to be in force up to and including January 31, 2025, for applications of permission for a clinical drug trial which have been submitted before January 31, 2022.
6. The repealed law is in force for a clinical drug trial up to and including January 31, 2025, if the application for permission for the clinical drug trial has been submitted after January 31, 2022, but before January 31, 2023, and if the sponsor has requested that the application be processed under the repealed Act.