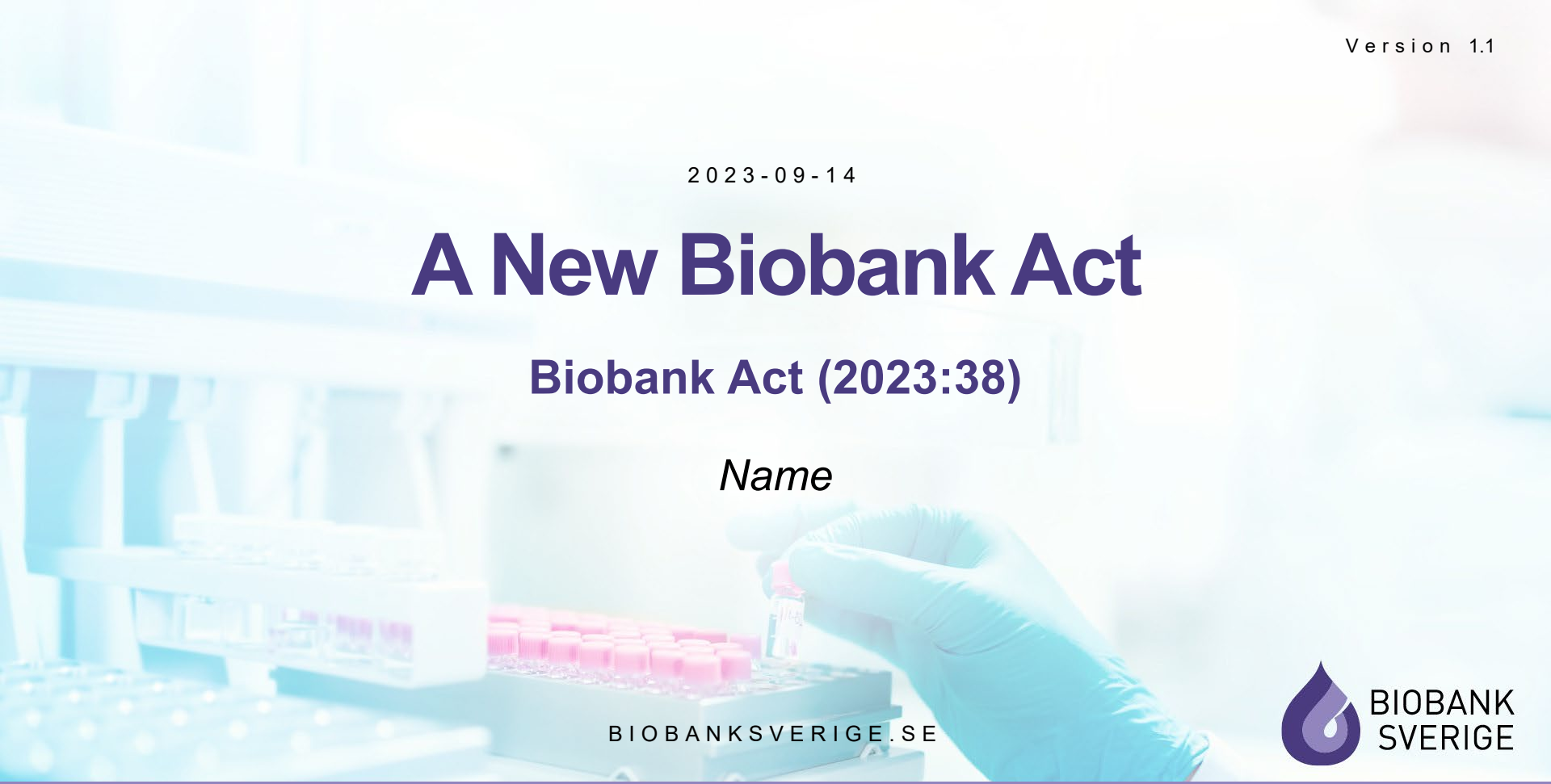
Version 1.1

2023-09-14

A New Biobank Act

Biobank Act (2023:38)

Name



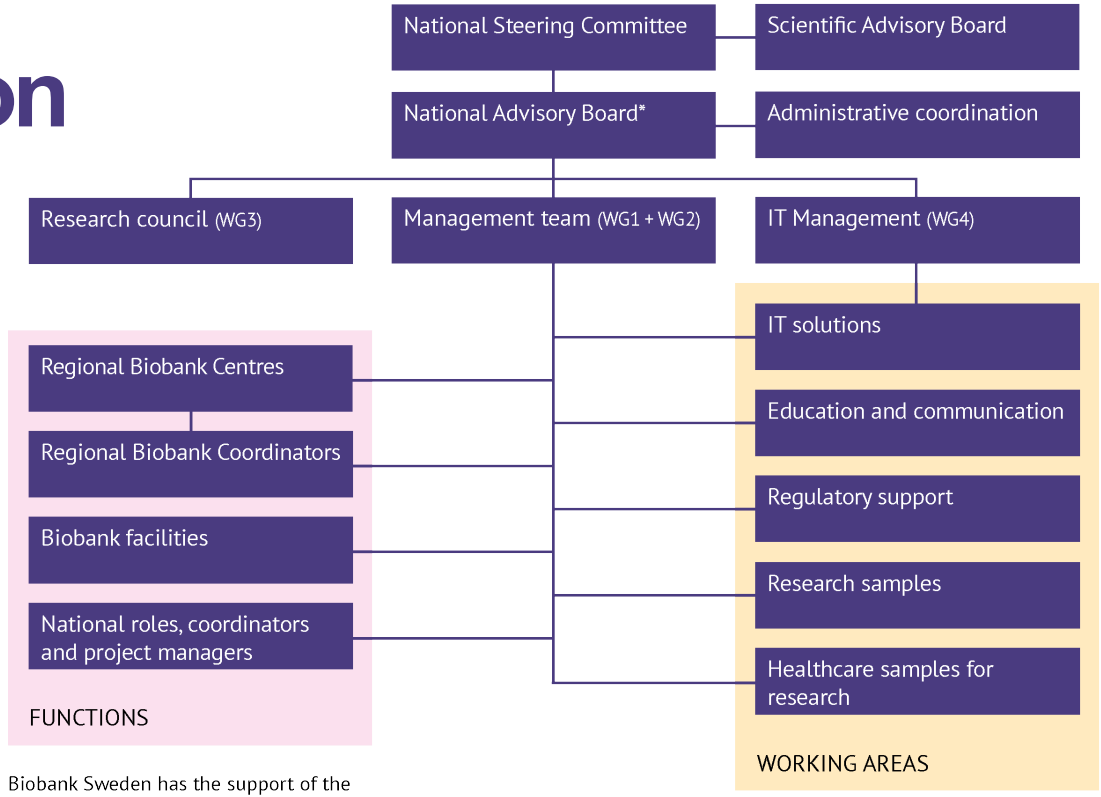
BIOBANKSVERIGE.SE

BIOBANK SVERIGE

What is Biobank Sweden?

Biobank Sweden is a national infrastructure for biobanking where healthcare, academia, industry and patient organisations collaborate to attain good healthcare and research.

Organisation



Biobank Sweden has the support of the Swedish Associoation of Local Authorities.

WG = Working group
** Executive group in the application to the Swedish Research Council.*

Regulatory and operative service

- Biobank coordinators
- Regional Biobank Centres
- Operative biobank service
- Sample service coordinators

National documents

- Templates
- Instructions
- Information materials
- Steering documents

Link to all documents at biobanksverige.se

Decision and application

- **25 January 2023** – the Riksdag (the Parliament) decided on a new Biobank Act.
- **1 July 2023** – the new Biobank Act entered into force.
- **Preliminary Q1 2024** – the National Board of Health and Welfare's regulations start to apply.

The new Biobank Act

- The new Biobank Act is named **Biobank Act (2023:38)**.
- **The purpose of the new Biobank Act** is the same as before; to regulate how identifiable samples, while respecting the integrity of the individual, may be collected, stored and used for certain purposes.
- Link to Biobank Sweden's unofficial translation of the Biobank Act (2023:38)
- Link to Biobank Act (2023:38) at riksdagen.se (Swedish only)

Biobank Sweden's assignment from the regions

All regions have signed a collaboration agreement on a common implementation of the new Biobank Act.

Biobank Sweden has been assigned to lead a national implementation project.

Collaboration with academia, industry and patient organisations takes place within the framework of the regions' implementation project.

Regional contact person

Each region has appointed a person to be the national implementation project's regional contact.

Contact person in *fill in name of region* is *fill in the name and contact information of the contact person*.

The implementation project also includes Regional Biobank Coordinators, Regional Biobank Centres (RBC) and Regional Operative Biobank Services.

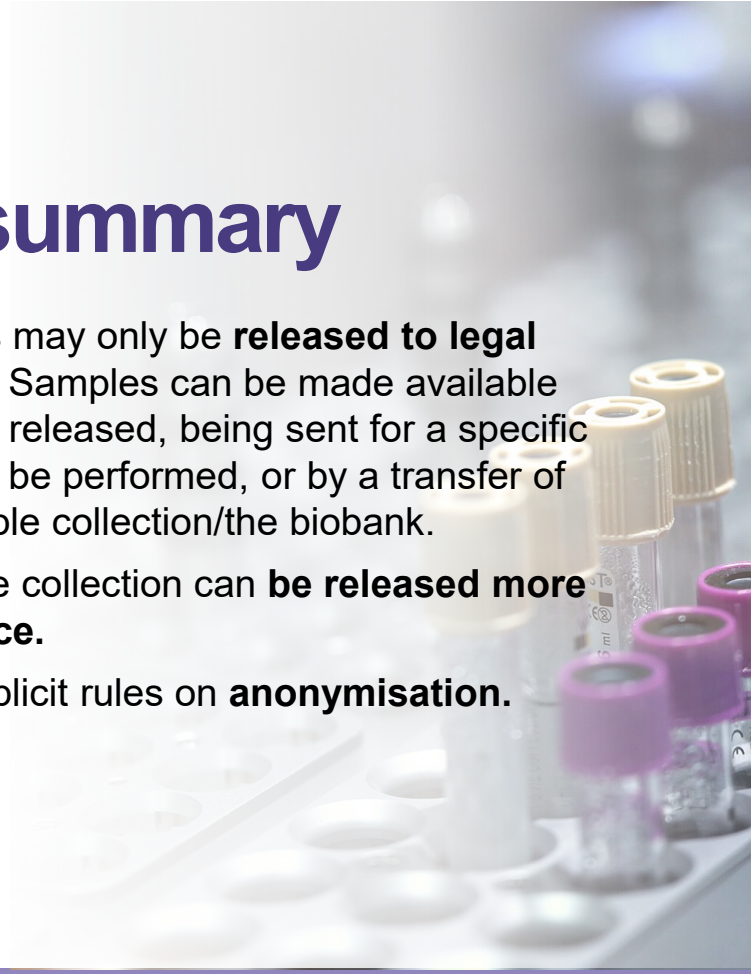
National implementation project

The project works for:

- A **national coordination** and an **uniformed application** of the new Biobank Act.
- **Reduced costs** for regions to implement and comply with the law.
- **Equal treatment** regardless of where a patient seeks care and/or participates in a study.
- **Increased accessibility** to samples taken in healthcare for research, clinical trials of medicinal products and medical devices.

The New Biobank Act – a summary

- Only **identifiable samples** are covered.
- **The purposes** for which samples are collected, preserved and used govern the applicability of the Biobank Act.
- Samples that are **analysed within nine months of sampling and destroyed immediately after the analysis** are not covered by the Biobank Act.
- General **subsidiarity** is removed.
- **Secondary biobanks** are removed.
- **Samples may be stored abroad.**
- Samples may only be **released to legal entities**. Samples can be made available by being released, being sent for a specific action to be performed, or by a transfer of the sample collection/the biobank.
- A sample collection can **be released more than once.**
- More explicit rules on **anonymisation.**



The purpose determines the application

The Biobank 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.

Samples taken outside of healthcare are also covered if they are collected, stored or used for the purposes covered by the Biobank Act.

The Biobank Act applies if and when a purpose of a sample is changed to one of the purposes covered by the Act.

Samples exempt from the Act (1/2)

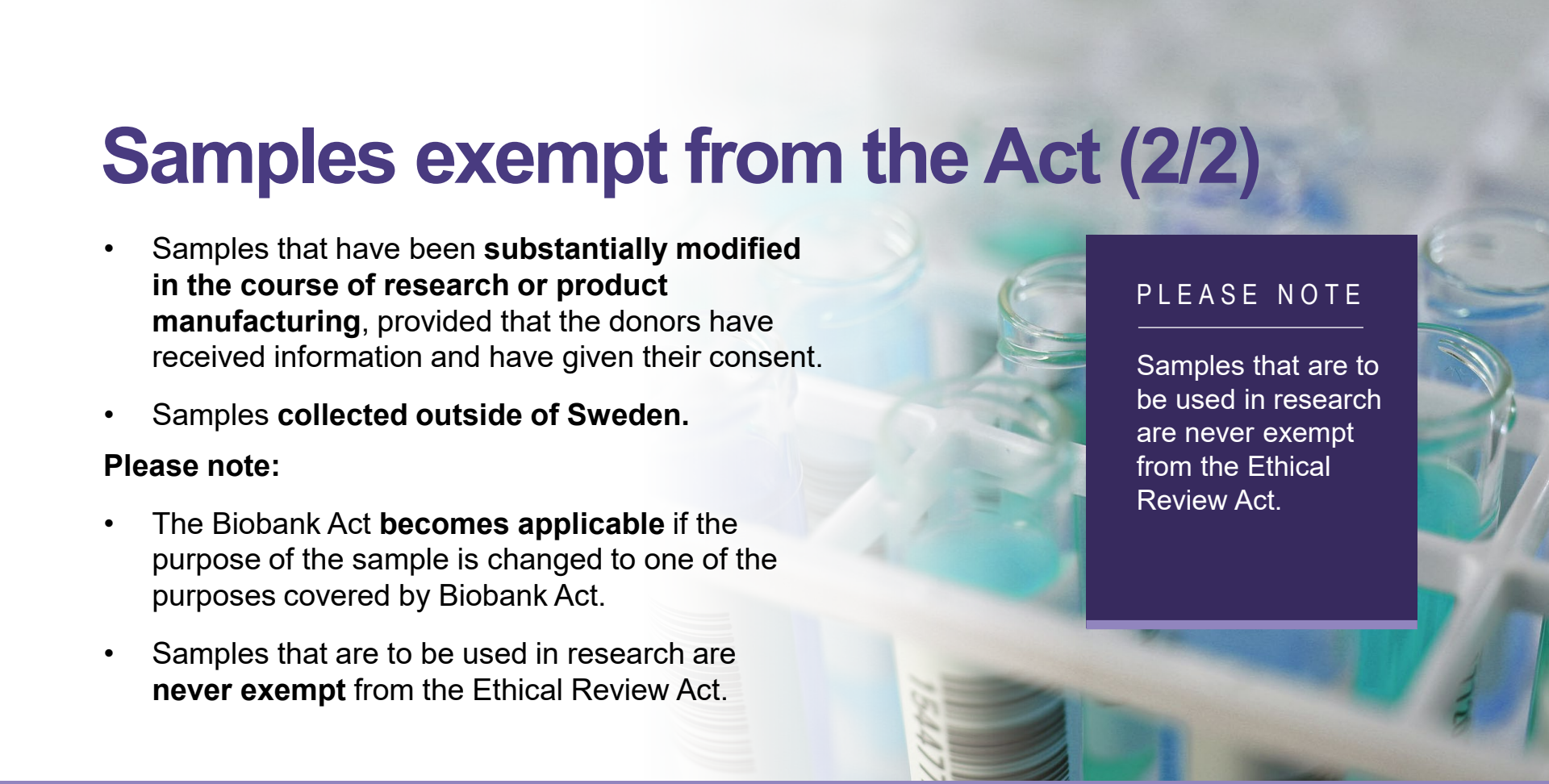
- Samples intended to be destroyed **within nine months of sampling and are destroyed immediately after analysis.** Both conditions must be met.
- Samples that are **anonymised**.
- Samples for **transfusion, transplantation, insemination** or **fertilisation outside the body**.
- Samples used in situations covered by **privacy protections in other laws.**
- Samples to be **included in medicinal products or medical devices**. These are rather to be considered as material.

Samples exempt from the Act (2/2)

- Samples that have been **substantially modified in the course of research or product manufacturing**, provided that the donors have received information and have given their consent.
- Samples **collected outside of Sweden.**

Please note:

- The Biobank Act **becomes applicable** if the purpose of the sample is changed to one of the purposes covered by Biobank Act.
- Samples that are to be used in research are **never exempt** from the Ethical Review Act.



PLEASE NOTE

Samples that are to be used in research are never exempt from the Ethical Review Act.

Consent (1/2)

- **Consent to collect and preserve samples within healthcare** are no longer required if the patient consents to the care.
- Clearer rules on **what information to be provided to sample donors.**
- If the sample donor **does not want samples to be preserved**, the sample should as a rule be discarded.
- A **limitation of** consent or that samples **may not be used** must be documented in patient's medical records or registers.
- Samples from children can be preserved **against parental consent** if there are special reasons. The child must receive information and give consent no later than when he/she turns 18.
- Samples may be collected and preserved for treatment **without the consent of the incapacitated**. However, there are uncertainties regarding the use of existing healthcare samples for research. The Government is investigating this as a separate issue.

Consent (2/2)

- A **new consent is not required for the use of stored healthcare samples** for quality assurance, development work and education **within** the healthcare system.
- Samples **taken specifically to be preserved** for quality assurance, development work and training **require consent** in accordance with the Biobank Act.
- **Research does not require consent under the Biobank Act**. The Ethical Review Act or the EU Regulations on Clinical Trials shall apply.

Terminology (1/2)

- **Biobank –** One or more sample collections held by one and the same principal. **Changed**
- **Sample collection –** One or more samples kept for a specific purpose in a biobank. **New**
- **Principal of a biobank –** Legal entity responsible for a biobank. **Changed**
- **Healthcare –** Activities covered by the Health and Medical Services Act (2017:30) or the National Dental Service Act (1985:125). **Unchanged**

Terminology (2/2)

- **Healthcare provider –** Any organisation who according to the Health and Medical Services Act or the National Dental Service Act is a healthcare provider. **Changed**
- **Sample –** Biological material from a living or deceased person or from a foetus. **Previous tissue sample**
- **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. **A clarification, not substantive change**
- **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. **New**
- **Anonymisation –** 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. **New**

Who will be affected by the new Biobank Act?

- **Principals and businesses** that use samples covered by the Biobank Act, primarily healthcare, academia and industry.
- **Activities within healthcare** where samples are ordered, taken, analysed and stored.
- **Patients and sample donors.**
- **Suppliers of IT systems to healthcare.**

Responsibilities of the principal

Responsibilities for biobanks is divided between the principal and the biobank custodian.

- **The principal** of a biobank is a legal entity, such as healthcare providers, universities or companies.
- **The principal** decides whether a biobank should be established and is responsible for reporting it to the Health and Social Care Inspectorate (IVO).
- **The principal** decides who will be responsible of the biobank and what purposes the biobank will be used for.
- **The principal** is responsible for ensuring that there are prerequisites for the biobank to operate in accordance with the requirements of the Biobank Act.
- **The principal** is responsible for the processing of personal data carried out in connection with the handling of samples according to the Biobank Act.
- **The principal** may decide to close down a biobank or a sample collection.
- **The principal** is responsible for re-evaluation of the biobank custodian’s decision regarding making samples available at the request of an applicant.

Responsibilities of the biobank custodian

Responsibilities for biobanks is divided between the principal and the biobank custodian.

- **The biobank custodian** is always a natural person.
- **The biobank custodian** decides if a sample collection is to be established.
- **The biobank custodian** decides for what purposes a sample collection can be used.
- **The biobank custodian** is responsible for ensuring that operations are conducted in accordance with the requirements of the Biobank Act.
- **The biobank custodian** is responsible for ensuring that samples are destroyed or anonymised if a sample may no longer be stored in a biobank.
- **The biobank custodian** is responsible for ensuring that a sample is destroyed immediately upon withdrawal of consent.
- **The biobank custodian** is responsible for assess applications regarding access to samples.
- **The biobank custodian** is responsible for establishing agreements when samples are to be sent for an action, e.g. analysis.

More information

Information page about the act:
English: The Biobank Act - biobanksverige.se
Swedish: Biobankslagen - biobanksverige.se

Summery of the new act:
Document in English (pdf)
Document in Swedish (pdf)

Link to Biobank Act (2023:38):
English: Biobank Sweden's translation of the Biobank Act (2023:38) (biobanksverige.se)
Swedish: Biobankslag (2023:38) (riksdagen.se)

FAQ: In Swedish. Frequently Asked Questions about the new act that is updated regularly can be found at biobanksverige.se/faq/

Contact

Do you have questions about the project or the Biobank Act?

Contact Biobank Sweden:
info@biobanksverige.se

Some questions related to the new law may take longer to answer due to the ongoing work.