Dokument: *B1. Glossary*
Version: *10.3* ***Date:*** *2025-05-23*
Established by: *Ledningsgruppen på uppdrag av styrgrupp för Biobank Sverige*

The Regions' joint biobank documentation

Glossary

Summary: A cooperation agreement was signed by the Directors of Health Care in 2022 with the aim of achieving national coordination and uniform application of the Swedish Biobank Act. Biobank Sweden was commissioned to lead a national joint implementation project. Within the framework of the project, and with the support of the Swedish Association of Local Authorities and Regions (SALAR), common interpretations and routines are being developed, as well as common information and training material and forms.

This glossary contains terminology linked to the Swedish Biobank Act (2023:38) and the procedures for handling biobank samples created as part of The County Councils' Biobank Project, now Biobank Sweden.

Biobank Sweden is a national infrastructure for biobanking, available at a regional level and established through collaboration between healthcare, academia, industry, and patient organisations. The infrastructure aims to give Sweden the best prerequisites for healthcare and research within the biobank area, both nationally and internationally. Biobank Sweden also works to facilitate the implementation of the Swedish Biobank Act. The work is run by order of, and with the support of, regions and universities with medical faculties. The work is also supported by the Swedish Association of Local Authorities and Regions, The Swedish Research Council and Vinnova by means of Swelife. For more information, go to www.biobanksverige.se.

REVISION HISTORY

Version	Date	Responsible	Changes
10.0	2023-04-20	Gunilla Bergström	The first new version was never translated to English.
10.1	2024-01-12	Gunilla Bergström	First translated version.
10.2	2024-10-31	Gunilla Bergström	Definition of cohort added.
10.3	2025-05-23	Gunilla Bergström, Sonja Eaker Fält	Clarification under the terms "withdrawal" and "retrieval"

INNEHÅLL

INDEX

1 Document information

1.1 Purpose and introduction

The glossary is one of the main documents that the regions, via Biobank Sweden, have jointly produced to obtain a nationally uniform interpretation of the Swedish Biobank Act and to create common routines.

The glossary is managed and updated by Biobank Sweden. The glossary contains terminology concerning biobank samples and guidelines on how to utilise the samples in healthcare and research in addition to how samples can be released to other principals for this purpose. Certain organisational terms regarding biobank liability are also included.

The purpose of this glossary is to standardise the terms used in the biobank area. It may also serve as a support for people in various organisations who are responsible for handling decisions on biobank issues.

A summary of the regions' shared biobank documentation can be found in the document *Dokumentförteckning* (document A2, Swedish only).

1.2 Definitions

The glossary is a document that is regularly revised due to, among other things, the entry into force of new laws.

1.3 Reference documentation

For some terms in the glossary, the source is explicitly stated in the source field. However, a number of concepts are based on the compilation and processing of information from a number of sources. Biobank Sweden is then cited as the source. The documents in the list below are both those referred to in the explicit references and those used as more general background information.

Abbreviation	**Title**	**Issued by**
The Biobank Act	a. The Swedish Biobank Act (2023:38)	b. Ministry of Health and Social Affairs
The proposal	c. Government proposal 2021/22:257 A new Biobank Act	d. Ministry of Health and Social Affairs
CIS 10/2003	e. Instructions National Reserve number	f. Carelink
CONTSYS	g. Contsys “System of concepts to support continuity of care” (European preliminary standard). Swedish standard: SS-EN ISO 13940:2016 Health informatics – system of concepts to support continuity of care.	h. CEN, ENV 13940
Dybkaer	i. Vocabulary for use in measurement procedures and description of reference materials in laboratory medicine	j. Eur J ClinChemClinBiochem

Abbreviation	Title	Issued by
The Ethical Review Act	k. The Act concerning the Ethical Review of Research Involving Humans (2003:460)	l. Ministry of Education and Research
eSam	m. Pseudonymisation of personal data, ES2022-01	n. eSam – public collaboration for increased digitalisation
IUPAC	o. Compendium of analytical nomenclature. Definitive rules 1997	p. IUPAC (International Union of Pure and Applied Chemistry)
National tissue documentation, glossary	q. National tissue documentation, glossary 2.0.	r. The Swedish National Council for Organs, Tissue, Cells and Blood
NE dictionary	s. NE dictionary	t. NE dictionary
Nordisk förvaltningsordbok/Nordic administration dictionary	u. Nordic administration dictionary	v. The Nordic Council
The Patient Data Act	w. The Patient Data Act (2008:355)	x.
GDPR	y. General Data Protection Regulation, the Data Protection Regulation. 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 movement of such data, and repealing Directive 95/46/EC (GDPR)). For more information, visit the website of The Swedish Authority for Privacy Protection (IMY).	z. The European Commission
Swedish National Board of Health and Welfare terminology database	æ. Swedish National Board of Health and Welfare terminology database http://termbank.socialstyrelsen.se/	bb. The Swedish National Board of Health and Welfare
SoS Information Leaflet	cc. National Board of Health and Welfare information leaflet, “Questions about the application	dd. The Swedish National Board of Health and Welfare

Abbreviation	Title	Issued by
	of the Biobanks in Medical Care Act", August 2003.	
TNC 98 New version (supersedes TNC 98): TNC 104	bb. Tekniska basord (Technical Keywords) ff. Basord i våra fackspråk (2012) (Keywords in our technical language)	gg. The Swedish National Centre for Terminology, TNC
Transplant Act	ee. The Swedish Transplants Act (1995:831)	ff.

1.4 Reading instructions

The glossary has been organised systematically, i.e., the terms are grouped by theme under six main headings. Underlined terms in running text mean that these terms can be found in a separate term entry (i.e., under the same subheading). The same term is only underlined once per term entry (its first instance). The alphabetical index facilitates quick glossary searches. *Italicised terms* in the index do not have their own term entries, instead they are dealt with in connection with other terms.

2 The concept of biobank and related concepts

2.1 biobank

one or more sample collections held by one and the same principal.

Note: Samples are stored in a biobank for one or more purposes. Storage may in itself be a purpose. Other purposes are regulated by different regulatory frameworks, e.g., the Biobank Act. The Biobank Act regulates the handling of human biological material. Other legislation such as the General Data Protection Regulation (GDPR) and the Patient Data Act (PDL) regulate the handling of the information linked to the material.

Biobanks covered by the Act consist of sample collections that are collected, preserved or used for the purposes specified in the Act. The Biobank Act does not apply to samples collected, preserved or used for transfusion, transplantation, insemination or fertilisation outside the body. Nor does it apply to a sample which, in the case of transfusion or transplantation, is preserved only for quality assurance purposes, or to samples collected, preserved or used for inclusion in medicinal products or medical devices. However, if samples preserved for one of the exempted purposes are to be used for other purposes, such as research, the Biobank Act will start to apply. Samples must then be included in a sample collection in a biobank.

A biobank is managed by an organisational unit. This is found at different organisational levels at different principals (directly under the principal, at another level in the line organization, as a staff function, etc.). Compare – biobank custodian.

Biobanks can also be established at government agencies such as universities and colleges as well as at private companies.

The term biobank is also used for the organisational unit. In order to avoid misunderstandings, it should be clarified whether it is the collection of human biological material or the organisational unit that is referred to. Compare – establish a biobank and close a biobank.

Source: The Biobank Act, Biobank Sweden

2.2 Swedish Biobank Register

Abbreviation: SBR

the regions' joint register of all samples taken within the Swedish healthcare system and preserved in a biobank

Note: The Swedish Biobank Register is intended to create such traceability that stored samples can be found when consent is withdrawn/restricted. The system shall also be a tool for research and operational development so that, while respecting the integrity and self-determination of the donor, valuable samples can easily be located for research if the donor has not opposed such use. It can also facilitate the search for previously taken samples from the same donor for the donor's own care and treatment. The development, operation, and management of SBR take place within the framework of a collaboration agreement between all regions.

Source: Biobank Sweden

2.3 biobank department

department subordinate to the organisational unit that has the biobank

Note: This is not a legal term under the Biobank Act. Certain organisational units that have biobanks also have biobank departments. Biobank departments are primarily found in regions where the principal has established only one biobank or a few biobanks with sub-departments. Compare custodian of biobank department.

Source: Biobank Sweden

2.4 e-biobank

register containing information about samples taken within research studies which are immediately released (see release) following sampling or that according to agreement immediately become part of a sample collection at the research principal/sponsor who are responsible for the study

Note: The e-biobank only has virtual sample collections, i.e., the sample collections only consist of information about samples and not the actual samples. At the receiving principal, the samples will be part of a sample collection in a newly established or an existing biobank.

Source: Biobank Sweden

2.5 multicentre study

research study involving sampling at more than one site

Source: Biobank Sweden

2.6 sample collection

one or more samples that are stored in a biobank for a certain purpose

Note: The biobank contains one or more sample collections. The Biobank Act refers to human biological material as samples or identifiable samples.

It is the person responsible for a biobank who decides if a sample collection should be established.

An individual sample in a biobank may belong to many sample collections, depending on which characteristics or combination of characteristics the sample collection is specified by. Common characteristics may be where the samples are stored, biobank affiliation, donor, research studies etc., and reasons for grouping samples into sample collections may, for example, be a description of the division of responsibilities and right of disposition of samples. Each sample collection has a sample collection controller.

Note that biobanks may contain sample collections with samples that are not covered by the Biobank Act, for example sample collections with anonymised (see anonymisation) samples or samples collected outside of Sweden.

Source: the Biobank Act, Biobank Sweden.

2.7 Cohort

a group of people who have a common defining factor, e.g. were born in a certain year, have attended a particular school, received a certain vaccine, or participated in a certain health examination.

In epidemiological research, the purpose of a cohort is usually to follow the individuals over time to determine distinctive characteristics, e.g. answer the question of whether non-smokers live longer than smokers. A cohort study is therefore usually longitudinal. The group (cohort) can of course also be studied in cross-sectional (only one time, e.g. answer the question of whether non-smokers have lower blood pressure than smokers) but then it is not usually referred to as a cohort study.

In the context of biobanks, special opportunities arise in a cohort study if the common factor is that everyone in the cohort has submitted a biological sample to a certain sample collection that can be used for future research. In such a cohort, it is possible to subsequently select only certain individuals' samples for an analysis based on the health outcome of the individuals, e.g. answer the question of whether women who later in life develop cervical cancer have more traces of HPV infection than others. The analysis does not need to be done on the entire cohort, but only on those who have contracted the disease and a number of comparison subjects. Another possibility that arises is that it is possible to measure properties in samples that were not relevant for research when the sample was taken, e.g. using modern 'omics methods' on samples taken 20 years ago or more.

Source: Biobank Sweden

2.8 sample

biological material from a living or deceased person or from a foetus

Note: Human biological material is referred to as a sample, regardless of its form or the sampling method. Samples taken directly from a sample donor may be called primary samples. A sample created from another sample may be called sub-sample. However, in most cases the context indicates whether a sample is a primary sample or a sub-sample, and it is not always necessary to identify what is what. This means that “primary” and “sub-” are usually not included. In SS-EN ISO 20387:2021, sample has the following definition: portion of a whole.

Source: Biobank Sweden, SS-EN ISO 20387:2021

2.9 identifiable sample

sample whose origin can be directly or indirectly traced to the human being or foetus from which the sample was taken.

Note: The Biobank Act only covers identifiable samples

Source: the Biobank Act

2.10 biobank sample

term for samples covered by the Biobank Act, i.e., identifiable human biological samples that are stored in a biobank for more than nine months after sampling. In practice, a biobank sample can be anything from fluids such as blood, urine and saliva to a cell or tissue sample, etc. Note that DNA/RNA extracted from a sample is also counted as a biobank sample.

Note: It is the purposes for which samples are collected, preserved or used that determine whether the Biobank Act is applicable or not.

The Biobank Act applies to identifiable samples collected and preserved in a biobank or used for the purposes of

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.

The fact that it is the purpose that determines whether the law is to be applied or not means that it does not matter where samples are collected. Samples taken outside the health care system are also covered if they are collected, preserved, or used for the aforementioned purposes according to the law.

The Act becomes applicable to samples that have been collected for a purpose not covered by the Act, if and when the sample becomes relevant for use for one of the purposes covered by the Act.

Identifiable samples exempt from the law:

- Samples that are kept for less than nine months after sampling and destroyed immediately after the analysis is completed.
- Materials collected, preserved, or used for transfusion, transplantation, insemination, or fertilisation outside the body, as well as samples kept for the sole purpose of quality assurance in the case of transfusion or transplantation.
- Materials collected, preserved, or used for the purpose of incorporation into medicinal products or medical devices.
- Samples that have been substantially modified within the framework of research or product production, if the sample donor has been informed that samples will be substantially modified and has given consent thereto.

Source: the Biobank Act, Biobank Sweden

2.11 newly collected research samples

samples that are taken for a specific research study. Samples must always be established as a sample collection in a biobank.

Source: the Biobank Act, Biobank Sweden

2.12 existing healthcare and research samples

Healthcare samples stored in the regions' biobanks and taken within the healthcare system **for the sample donor's care, diagnostics, and treatment**. These samples belong to the healthcare provider's biobank. Existing healthcare samples also include newly taken samples that are handled according to routines by a clinical laboratory such as a pathology unit, as an assessment is required of which part/volume can be used for research without affecting the diagnostics.

Research samples taken during a now completed research study where consent to the preservation of samples after study completion and for future research exists. Samples preserved during a study are also existing samples.

Note: In order to gain access to **existing healthcare samples**, a decision is required by the biobank custodian, whose task includes to ensure that the sample collection controller assesses whether sufficient material remains for possible future care, diagnostics and treatment. Terms and conditions for access to these samples are regulated in the existing agreement/biobank agreement between the sample collection controller and the biobank custodian.

In order to gain access to **existing research samples** for a new research study, it must be considered that such access would not interfere with ongoing research. When deciding on access to existing samples for the purpose of new research, it shall, among other things, be considered what the person responsible for the purpose for which the sample was collected and preserved requires to fulfil his or her responsibility. New research requires a new ethical approval and a new biobank application, which the biobank custodian formally decides upon following the sample collection controller's approval.

Source: Biobank Sweden

2.13 sample ID

identification code for samples

Source: Biobank Sweden

2.14 biobank coordinator

Note: The regions have chosen to delegate responsibility for the coordination of the principal's biobanks to a biobank coordinator. The biobank coordinator is a knowledge resource for healthcare, researchers, companies, and the general public regarding all biobank activities. The biobank coordinator offers guidance to researchers and companies concerning the Biobank Act, biobank applications and biobank service.

Source: Biobank Sweden

2.15 sample service coordinator

sample service coordinators (PSK)) for research provide operative services and are located at university hospitals. PSKs work primarily with guidance and support in the start-up of national studies that want to collect liquid-based samples. In addition to the service assignment, PSKs have a strategic function that aims to develop local work into a nationally coordinated biobank service. This will improve the opportunities for researchers to conduct research on biobank samples and provide support in the context of national research that uses biobank samples.

2.16 principal

government agency or organisation which is legally and financially responsible for certain activities

Note: There are several forms of principal, e.g., healthcare provider, research principal and biobank principal. The principal of a biobank is always a legal entity, e.g., a region, a company or a government agency such as a university.

The Biobank Act specifies the obligations of the biobank principal. 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 the Biobank Act. The principal is also responsible for the processing of personal data that is carried out in connection with the handling of samples in accordance with the law.

Source: Nordisk förvaltningsordbok/Nordic administration dictionary, the Biobank Act.

2.17 biobank custodian

person delegated by the biobank principal to be responsible for a biobank and the organisational unit that manages it

Note: In connection with the decision to establish a biobank, the principal must appoint a biobank custodian and determine the purpose of the biobank. The regions have organised their biobanks and division of responsibilities in different ways. This means that there may be biobank custodians on several organisational levels. The biobank custodians are responsible for ensuring that operations are conducted in accordance with the requirements of the Biobank Act.

Source: the Biobank Act, Biobank Sweden

2.18 custodian of biobank department

person within a biobank principal's organisation appointed to oversee a biobank department

Note: In cases where the biobank has biobank departments, each sub-department will have a custodian. Note that custodian of biobank department is not a legal term according to the Biobank Act.

The custodian of biobank department is responsible for ensuring that the biobank department's area of operation complies with the requirements of the Biobank Act. Compare sample collection controller.

Source: Biobank Sweden

2.19 research principal

the legal entity that has the ultimate responsibility for the research and applies for ethical review, and in addition is responsible for ensuring that the application is complete. The research principal is responsible for ensuring that research covered by the Ethical Review Act is not carried out without approval and needs to take measures to prevent this from happening. The research principal is also responsible for ensuring that the research is not carried out in violation of any conditions announced in connection with an ethical approval. This implies an organisational responsibility to act within the entity's own operations. For example, the principal needs to ensure that there are good procedures in place for information, follow-up, and control regarding issues of ethical review within the organisation. The research principal must also ensure that those who work with research receive the necessary training on the Ethical Review Act and what is required according to the Act.

Source: The Swedish Ethical Review Authority

2.20 principal investigator

person with the main responsibility for conducting a research study that is not a clinical trial of medicinal products

Note: In this context, the principal investigator is the person named as 'ansvarig forskare' [lead researcher] in the application submitted to the Swedish Ethical Review Authority and its subsequent decision.

Note that Swedish terminology makes a distinction between the term 'ansvarig forskare', which refers only to the person responsible for a research study that is not a clinical trial of medicinal products, and the term 'Principal Investigator'; in cases of clinical trials of medicinal products, the latter term is used to conform to the common terminology of the EU.

According to EU regulations, the principal investigator is the investigator who is the responsible leader of a group of investigators conducting a clinical trial at a trial site.

Source: Biobank Sweden

2.21 sponsor

person, company, institution or organisation responsible for initiating, managing and arranging for the financing of a clinical trial/performance study

Note: Commercial sponsor – company-initiated clinical trial. Non-commercial sponsor – investigator-initiated/academic clinical trial

With the application of the new EU regulations for clinical trials of medicinal products (EU) No 536/2014 and for medical devices (EU) No 2017/745 and (EU) 2017/746, Biobank Sweden's use of the term "sponsor" needs to be defined as above, while the term research principal/national coordinating investigator is removed. According to EU regulations, the Principal Investigator is the investigator who is the responsible leader of a group of investigators conducting a clinical trial at a trial site.

Source: EU regulations (EU) No 536/2014, (EU) No 2017/745 and (EU) No2017/746

2.22 sample collection controller

person who is responsible for one or more sample collections (see sample collection) within a biobank.

Note: Samples included in the sample collection may have been collected for clinical purposes (in which case the supervisor for the clinical discipline may be the sample collection controller), or for research purposes (in which case the researcher is the sample collection controller). Note that sample collection controller is not a legal term according to the Biobank Act. The person legally appointed by the principal to be responsible for the biobank is the biobank custodian. For research, a sample collection controller's access to samples for research is regulated by the biobank agreement established between the researcher acting as sample collection controller and the biobank custodian.

Compare custodian of biobank department and biobank custodian.

Source: Biobank Sweden

2.23 Regional Biobank Centre

Abbreviation: RBC

organisational unit within a healthcare region responsible for the overall coordination of biobank issues in accordance with the Biobank Act and its nationally agreed application

Note: Each healthcare region has an RBC, although the organisational forms vary somewhat between the healthcare regions. RBC is a service and knowledge centre based in a healthcare region and shall, among other things, be a resource for the regions in the healthcare region, be responsible for the healthcare region's part of the Swedish Biobank Register, and administer cases and make decisions on requests for amendments to studies where previous decisions have been made according to the multicentre principle before 1 July 2023. The RBC carries out a review and submits a statement to the Swedish Medical Products Agency and the Swedish Ethical Review Authority regarding the application for a clinical trial of medicinal products according to CTR, and reviews the associated biobank application.

Each RBC is managed by an *RBC manager*.

Source: Biobank Sweden

2.24 establish biobank

determine resources, powers and responsibilities for the organisational unit that will manage a biobank

Note: It is the legal entity that establishes a biobank that becomes the biobank principal. In connection with the establishment of a biobank, its purpose is determined and a biobank custodian is appointed. When a biobank is established, the Swedish Health and Social Care Inspectorate (IVO) must be notified within one month from the decision to establish the biobank. The biobank will then be assigned a unique national registration number.

Source: the Biobank Act

2.25 close biobank or sample collection

cease operations within the organisational unit that manages a biobank or a sample collection

Note: The principal of a biobank may decide that the biobank or one or more sample collections are to be closed down. If a biobank is closed down, the principal of the biobank is responsible for reporting the decision to close the biobank to the Health and Social Care Inspectorate (IVO). The notification must include information on what has happened to the samples in the biobank.

If a biobank or sample collection is to be closed down but samples are to be taken care of by another biobank, the rules on transfer of biobank or sample collection must apply.

Source: the Biobank Act

2.26 healthcare organisation

an organisation regulated by the Swedish Health and Medical Services Act (2017:30) or the Swedish National Dental Service Act (1985:125)
Source: based on the Biobank Act

2.27 healthcare professionals

deprecated term: healthcare provider

persons who in their profession provide health and medical care

Note: Avoid the term healthcare provider for this concept.

Source: Swedish National Board of Health and Welfare terminology database

2.28 healthcare provider

an entity which, according to the Swedish Health and Medical Services Act or the Swedish National Dental Service Act, is a healthcare provider

Source: the Biobank Act

2.29 healthcare episode

all healthcare contacts with a patient regarding a specific health problem

Note: Note that in the interpretation of the Biobank Act, the term “healthcare episode” is also used for donors who are not patients with a specific health problem.

Source: Swedish National Board of Health and Welfare terminology database

2.30 patient medical records

one or more medical record documents (see medical record document) relating to an individual patient.

Source: Patient Data Act

2.31 medical record document

representation in written or image form and recording that can be read, listened to or otherwise accessed only by technical means, and that is produced or received in connection with the care of a patient, and that contains information about a patient's state of health or other personal circumstances, or about care actions taken or planned.

Note: Compare patient medical record

Source: The Patient Data Act

3 The concept of consent and closely related terms

3.1 consent

a freely given, specific and unambiguous expression of will by which a person that has been informed, prior to being asked, accepts the matter of the question

Note: This means that the person who has been informed and asked gives their consent or that they do not.

In order for a sample to be collected and preserved in a biobank, the sample donor must have given consent to this, unless otherwise stated in the Biobank Act or other legislation. The Biobank Act contains rules concerning consent regarding sample donors that are children, individuals that are incapacitated, investigation of patient injury and identification of deceased. If there are special provisions on information and consent in other laws, these provisions shall apply.

Consent is not required for care and treatment under the Biobank Act. Instead, it is the consent rules in the Patient Act (2014:821) or the Dental Service Act (1985:125) that are to be applied concerning collection and preservation of samples for healthcare purposes. The condition is that information has been provided in accordance with the requirements of the Biobank Act.

The information that is to be provided to the sample donor is for what purpose samples are collected and preserved in a biobank, the purpose of the sample collection and what the sample may be used for, which purposes that are permitted according to the Biobank Act and the right to withdraw or restrict their consent to collect, preserve or use a sample.

The Biobank Act does not specify as to when the information must be given in relation to the consent to receive care or treatment. If a need to preserve an exempt routine sample arises, the consent given to receive care or treatment can be supplemented with information afterwards. However, the information must be provided at the latest in connection with the collection and preservation of samples.

When samples have been taken on the basis of the consent given to receive care or treatment, they may also be preserved for future quality assurance and development work in health care activities and education conducted in connection with health and medical care. Samples may also be used for these purposes, unless the sample donor has objected to such use. Samples may also be preserved for future research. In order for samples to be used for research, an ethical approval is required. See below.

The donor can object to the collection, preservation and use of the sample at any time.

When it comes to samples from children, it is the child's legal guardian who must be informed and who can give consent or oppose the collection, preservation, or use of a sample. However, the child's level of maturity must always be taken into account. If the child has reached such an age and maturity that the child can judge the matter to which the information applies, the child can give consent.

When it comes to samples collected from a deceased person, it is the consent rules in the Transplant Act and the Autopsy Act that are applicable. If the sample is taken for the purpose of research, there is a requirement for an ethical review.

There is a special rule for when a deceased person has given consent before the time of death. The sample may be used for a purpose other than that which was consented to only if the deceased's next of kin have been informed of, and after a reasonable period of consideration have not objected to, the new purpose.

Consent is not required for research under the Biobank Act. Instead, it is the information and consent rules in the Ethical Review Act (2003:460) that are to be applied.

In the case of a clinical trial in accordance with Regulation (EU) No 536/2014, the application to conduct a clinical trial must be granted authorisation before samples can be used. In connection with the ethical review of clinical trials that involve the use of biological samples from research participants, the Ethical Review Authority shall, in its assessment, propose what requirements that should apply in terms of information and consent for the use of the samples.

Decisions of consent concerning biobank samples for research purposes must be preceded by information in accordance with ethical approval. The content of the information is regulated in the Ethical Review Act and GDPR. The decision of consent is usually obtained in writing and must be appropriately documented in the patient's medical records.

Source: the Biobank Act, Biobank Sweden

3.2 incapacitated

Synonym term: *without decision-making ability*

(about sample donors:) who, due to illness, mental disorder, weakened state of health or other similar circumstances, is unable to adopt a position on the issue of the handling of the sample

Note: This may involve unconscious persons, psychiatric conditions and dementia diseases that render the sample donor unable to take a position on the issue of the handling of the sample. A person who, for some reason, cannot make up his or her mind or wants to reconsider his or her decision is not considered incapacitated. Nor are persons under the age of 18 considered incapacitated in the context of biobanks.

Compare: consent

Source: the Biobank Act, Biobank Sweden

4 The concept of donor and closely related concepts

4.1 sample donor

a living person from whom a sample has been taken, or a living person who carries or has carried a foetus from which a sample has been taken

Note: A sample donor can be a patient, a research participant or subject, a person undergoing a health examination, etc. If a sample is taken from a foetus, the person who carries or has carried the foetus is considered to be the donor.

A deceased person from whom a sample has been taken does not count as a sample donor as defined in the Biobank Act. If a sample is taken from a deceased person, the rules on consent set out in the Transplant Act and the Autopsy Act apply.

If the sample is taken for the purpose of research, there is a requirement for an ethical review.

Source: the Biobank Act

4.2 research participant

a living person who is the subject matter of the research

Source: the Ethical Review Act (2003:460)

4.3 subject

person participating in a clinical trial, either as a recipient of the investigational medicinal product or as a control subject

Note: In the Medical Devices Regulation (Article 2, paragraph 50), the definition is 'person participating in a clinical trial'.

Source: Clinical Trials Regulation (Article 2, paragraph 17)

4.4 sampling

procedure in which a sample is taken from a sample donor

Note: Compare sample.

Source: Biobank Sweden.

4.5 time of sampling

the occasion when a sample is taken from a sample donor

Source: Biobank Sweden

4.6 sampler

the person performing the sampling

Source: Biobank Sweden

4.7 client

the person ordering the sampling

Note: The client has overall responsibility for ensuring that information is provided and documented. This applies both within healthcare and research. In healthcare, the client is the person responsible for the patient's care and treatment.

Source: Biobank Sweden

4.8 sample ordering unit

the unit responsible for ordering sampling

Note: Compare client.

Source: Biobank Sweden

4.9 sample type

Note: The term *sample type* (as well as *type of sample*) should be used with caution in precise contexts, as it is used variously to refer to the location on the body where a sample has been taken, how the sample was prepared, as well as the sampling method used. Hence, there is a risk of misunderstanding. If the term *sample type* or *type of sample* still is used, it should be supplemented with phrases such as “where on the body the sample was taken”, “what kind of material the sample contains”, etc. See also: preparation.

Source: Biobank Sweden

5 The concept of personal data and closely related terms

5.1 personal data

information that can be directly or indirectly linked to a natural person

Note: GDPR uses the following definition of personal data: any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

In GDPR the definition is limited to living persons. The rules in GDPR do not apply to data about deceased persons, but other regulations contain provisions that also regulate the processing of deceased persons' personal data. The Patient Data Act, which regulates the processing of personal data in healthcare, also applies to deceased persons. Personal data of deceased persons may also be covered by confidentiality in accordance with the rules of the Public Access to Information and Secrecy Act.

Source: GDPR, the Patient Data Act, the Public Access to Information and Secrecy Act

5.2 data protection officer

person who has the task of ensuring that GDPR is followed within an organisation

Source: based on GDPR

5.3 personal data controller

the person who, alone or together with others, determines the purposes and means of the processing of personal data. To be responsible for personal data means to have the obligation to ensure that the processing of personal data complies with applicable laws, ordinances, and regulations.

The Biobank Act contains a provision stating that the principal of a biobank also becomes the personal data controller for the processing of personal data carried out in connection with the handling of samples under the Biobank Act. In this way, the responsibility for personal data in biobank operations is linked to the principal that established the biobank. See the section on principals.

The Patient Data Act contains another regulation concerning the responsibility of personal data for personal data processed under that Act. A healthcare provider is the personal data controller for the processing of personal data that the healthcare provider performs. In a region and a municipality, each authority that conducts health and medical care is the personal data controller for the processing of personal data that said authority performs.

Note: According to GDPR, a personal data controller can be a natural person or legal entity, public authority, agency, or other body

Source: the Biobank Act, GDPR, the Patient Data Act

5.4 personal data processor

the person who processes personal data on behalf of a personal data controller

Note: According to GDPR, a personal data controller can be a natural person or legal entity, public authority, agency, or other body.

A personal data processor is always an external party and may, for example, be a service agency that manages a biobank's IT operations, a cloud service provider, or another biobank which processes personal data on behalf of the personal data controller. A personal data controller may only engage personal data processors that can provide sufficient guarantee that the processing of personal data complies with GDPR and ensures that the rights of the data subject are protected.

Source: GDPR

5.5 personal ID

identification code for a natural person

Note: A personal ID may, for example, be a Swedish personal identity number or coordination number (a personal ID for someone who is not or has not been registered in Sweden) or reserve number (personal ID used in healthcare to link a patient with their healthcare information if no personal identity number is available, or if it is unknown), but also local IDs such as a disaster number, donor ID etc. Therefore, a person can have multiple personal IDs.

Source: Swedish National Board of Health and Welfare terminology database

5.6 personal data ID

identification code for personal data

Note: The term applies in connection with pseudonymisation of personal data.

Source: Biobank Sweden.

6 Concepts regarding the use of samples

6.1 preparation

deprecated term: sample type

(of sample:) treatment that prepares a sample for use

Note: Storage may also be a use. Do not use the ambiguous term “sample type” when referring to the results of a certain preparation.

Source: Biobank Sweden.

6.2 destruction

to deliberately destroy

Note: In Swedish biobanking terminology (as used in the Biobank Act) it is recommended to make a distinction between the verbs ‘destruera’ [destruct] and ‘förstöra’ [destroy], where the former emphasizes that the action is deliberate and the latter has a more general meaning, and to primarily use the former where applicable. Compare: anonymisation and discarding.

Source: based on the NE dictionary

6.3 destroy

in the meaning of the Swedish word “destruera”: carry out destruction; or, in the meaning of the Swedish word ”förstöra” (about sample): make unusable

Note: Samples can be destroyed both intentionally (Swedish: ‘destrueras’) and unintentionally (Swedish: ‘förstöras’). A destroyed sample does no longer exist as an individual sample. See also: destruction. Compare: anonymisation, destruction and discarding.

Source: based on the NE dictionary

6.4 destroy

see 6.3

6.5 discarding

removal of items that will no longer be used for their original purpose

Note: In standard language, discarding is often interpreted as something being thrown away and destroyed. As this is not always true in a biobank context, it is important, when using discarding and (to) discard, to specify the way the material will be handled following discarding (destruction, anonymisation, other use etc.). For example, a discarded sample may still be physically stored, but no longer be traceable.

Source: based on National tissue documentation, glossary

6.6 anonymisation

Synonym: *de-identification*

(of sample:) action resulting in the origin of a sample not being traceable, directly or indirectly, to the person or foetus from which the sample originates

Note: In the case of anonymisation, a sample continues to exist as an individual sample, but the possibility of identifying the sample donor via the sample has ceased. Total anonymisation is not really possible with human biological material because the material contains unique information that could identify the sample donor if further action is taken. However, in the context of biobanks, the term anonymisation is used for the situation when a sample can no longer be traced back to the person from whom the sample was taken through personal data. If actions are taken with an anonymised sample that means that samples and sample donors can be directly or indirectly linked, the sample will again become identifiable, and the handling of the sample will be regulated by the Biobank Act. It is also conceivable that a sample could be considered as indirectly identifiable if the sample can be linked to a very limited group of sample donors, even though the samples are not labelled with personal data that link them to a particular donor.

If consent is withdrawn for the preservation of a sample or for all use of the sample, the person in charge of the biobank is responsible for the immediate destruction of the sample. If it is not possible to destroy a sample without destroying other samples, the biobank custodian is responsible for the sample being immediately anonymised.

It is not permitted to anonymise samples in order to use them for anything other than what the sample donor has consented to.

Sometimes the term ‘discard’ is used to mean "anonymise and/or destroy" which is unclear and therefore inappropriate—see further under discarding. Instead, make a clear distinction between *anonymise* and *destroy* where appropriate, and use the full expression *anonymise* or *destroy* (the noun expression *anonymisation* or *destruction*, respectively) where both meanings are implied.

GDPR Recital 26 uses the term ‘anonymisation’ as a synonym of de-identification.
Compare: coding and pseudonymisation.

Source: the Biobank Act, GDPR

6.7 pseudonymisation

an identifier is replaced with a pseudonym that can only be linked to the identifier by means of a code key

Note: GDPR defines pseudonymisation as processing of personal data (see personal data) in a way that means

1. that personal data can no longer be attributed to a specific data subject without additional information (see coding) and,
2. that this additional information is kept separately and is subject to technical and organisational measures that ensure that the personal data are not attributed to an identified or identifiable natural person

In the Biobank Act, the term ‘coding’ is used for this concept. In the context of biobanking, pseudonymisation means that a code is put both on the sample (sample ID) and on the identity of the sample donor (personal data ID) with a code key between them.

Compare anonymisation and coding.

Source: based on GDPR

6.8 pseudonym

identifier that differs from the common method for identifying an object or person and that can only be linked to the original identifier by means of additional information that is stored separately and is not generally available

Source: based on eSam

6.9 coding

conversion of data from one form to another

Note: In the Biobank Act, the term 'coding' is used to refer to the replacement of an identifier with a designation that is not directly identifying. In other contexts, 'coding' is used when replacing a long name with a short – often fully identifying – code. In a biobank context, 'coding' usually refers to when directly identifying information on a sample is replaced with a sample ID, which can be directly linked to a personal ID using a laboratory information system. However, this is to be deemed a coded sample and not a pseudonymised sample as both the personal data ID and the code key are missing.

When the term 'coding' is used, the intended meaning should be clearly stated. Likewise, the term 'decoding' should be used with caution, as it is sometimes used synonymously with anonymisation of the sample and sometimes to denote using the code key to access the data behind the code/pseudonym.

In some cases, especially in the pharmaceutical industry, so-called double coding may occur. Double coding means, for example, that you go from personal ID number to a first code, and then from the first code to a second code, which is used, for example, when processing results. Note that both single coding and double coding are reversible and thus enable a link to the sample donor.

Source: TNC 104

6.10 code key

information that identifies the link between the data before and after pseudonymisation

Note: Can also be called pseudonymisation key.

Source: Biobank Sweden

6.11 service for research

Note: There are two forms of service functions that can be provided by either the same or different organisations.

Regulatory service for research: This includes, for example, advice on laws and agreements concerning access to samples for research, advice on biobank components in the application for ethical approval including patient information, and advice on the design of biobank agreements. A national coordination of this service is provided via Biobank Sweden's working group (for regulatory biobank service). The service is often provided by Regional Biobank Centres, or the region's biobank coordinator.

Biobank service for research: This includes operational sample services such as the management of sample collection procedures and support related to study planning, for example to ensure that collected samples are suitable for the question in the study. A national coordination of this service is provided via Biobank Sweden's working group (for operative biobank service). The service is provided by biobanks or other functions established by the principal for this purpose.

Source: Biobank Sweden

6.12 transfer

(in a biobank context:) the transfer of a biobank, sample collection or other biological material, together with full responsibility for its storage and use, from one principal to another principal

Note: A sample collection or biobank may only be transferred to a recipient in Sweden. A transfer entails that the responsibility for storing and using the samples is transferred to the recipient. The purpose of a sample collection does not change when it is transferred.

The sample collection or the biobank may only be transferred if there are special reasons and if the Swedish Health and Social Care Inspectorate decides to approve the transfer. Special reasons may be, for example, organisational changes, bankruptcy, or death.

Source: the Biobank Act

6.13 release

(in a biobank context:) the physical transfer of a sample collection or other human biological material and its accompanying information from one principal to another upon request from the other principal

Note: Once a sample is released, the responsibility and the right to use said sample is transferred from the releasing principal to the receiving principal. However, the releasing principal has a continued responsibility to retain documentation about samples and information about to whom samples have been released, to enable traceability of samples. Please note that the transfer of material between different biobanks within the same principal does not entail release. The purpose of release is that the principal to whom the material is released intends to use the material, preferably for research or clinical trials. Material from sample collections may be sent for assessment or analysis within or between principals without this being counted as release. The principal or biobank custodian of the releasing biobank is responsible for ensuring that the samples and personal data provided are pseudonymised (see pseudonymisation) so that the identities of the sample donors are not exposed.

Common to the various forms of making samples available that are regulated is that they all result in one or more biobank samples being physically moved from the original biobank principal's activities.

Source: the Biobank Act

6.14 making available

is a collective concept for when samples that are established in a biobank are made available outside the own principal. This can be done by sending samples for a specific action to be carried out, by release, or by transfer of the sample collection or the biobank in which the samples are included.

Note: A sample from a biobank may only be made available to legal entities. Samples can be sent for action within or outside Sweden. Release and transfer of samples can only be made to a legal entity with a corporate identification number in Sweden.

A sample that is made available shall be coded, unless this prevents the purpose of making it available. This applies to all forms of making samples available, i.e., release, sending samples for a specific action, and transfer. If a coded sample from a sample donor is made available at the same time as other personal data from the sample donor, the personal data must be made available in such a way that it cannot be linked to the sample by any unauthorised person. Human biological material may not be made available for profit.

Source: the Biobank Act, Biobank Sweden

6.15 access

refers to cases where the use of samples takes place within the principal.

Note: A researcher's access to samples is regulated in a biobank agreement.

Source: Biobank Sweden

6.16 retrieval

(in a biobank context:) to retrieve the requested sample from a research sample collection out of storage

Note: When biobanks provide services to researchers, samples can be taken from the researcher's sample collection to perform an action, e.g. carry out an analysis for the ethically approved research project to which the sample is linked, which is called retrieval. The healthcare system uses its own terms for when samples are retrieved from a sample collection for some kind of action, e.g. picking.

Retrieval is not the same as "withdrawal" as withdrawal means that a new sample collection is created. Retrieval and "withdrawal" are not legal terms but are about the practical handling within the same principal. The prerequisites are that the sample collection is established in the biobank and that there is an approved biobank application.

Source: Biobank Sweden

6.17 withdrawal

(in a biobank context:) to create a new sample collection by the withdrawal of a subset of samples from an already existing sample collection, all within the same principal's activities.

Note: Withdrawal and "retrieval" are not legal terms but are about the practical handling within the same principal. The prerequisites are that the sample collection is established in the biobank and that there is an approved biobank application.

Source: Biobank Sweden

6.18 action

(in a biobank context:) samples are sent for a specific action to be performed

Note: A sample may be sent to a legal entity for a specific action to be performed. In this case, the sample does not cease to be included in the biobank from which it was sent. When a sample is sent from a biobank for a specific action, the person responsible for the biobank must

1) establish an agreement with the recipient on the purpose of making the sample available and what is to be done with the sample after the action has been performed, and
2) set the following conditions for making samples available:
    a) that a sample stored at the recipient shall, at the request of the biobank custodian, be returned or immediately destroyed or, if it is not possible to destroy it without destroying other samples, be anonymised, and

b) that the recipient does not use samples for anything other than the stated purpose.

The action can be of different types, such as analysis, preparation, reformatting, and storage.

Source: the Biobank Act, Biobank Sweden

6.19 Swedish Ethical Review Authority

government authority for ethical review of research involving humans

Note: This authority is described in the Ethical Review Act

Source: based on the Ethical Review Act

6.20 Swedish Medical Products Agency

Swedish government agency under the Ministry of Health and Social Affairs, which is responsible for the approval and supervision of pharmaceuticals and herbal remedies and the supervision of cosmetics and medical devices

Note: Coordinates the authorisation process for applications under the Clinical Trials Regulation (CTR).

Source: Swedish Medical Products Agency, Biobank Sweden

6.21 access to samples for research

an agreed right to use samples, in accordance with the Biobank Act

Note: A researcher's access to samples is regulated in a biobank agreement (current templates can be found at www.biobanksverige.se)

6.22 right of disposition

Deprecated term: ownership

Note: Generally, right of disposition applies to a specific research study approved by the Ethical Review Authority. In some cases, right of disposition may be limited in time and scope. This must be described in the biobank agreement established between the biobank custodian and the sample collection controller.

The term *exclusive right* may also be used to denote right of disposition. The term *extended access* implies that a researcher who previously had the right of disposition must be consulted before a decision is made to enable other researchers to access samples subject to the right of disposition.

The term *ownership* is to be avoided, as in civil law it is not possible to talk of ownership of human biological material.

Source: Biobank Sweden

6.23 Material Transfer Agreement

Abbreviation: MTA ,

agreement between two parties regarding samples and accompanying information in the event that samples are sent from one party to the other party for analysis

Note: An MTA is used to regulate the parties' liability when samples are sent for analysis from a principal, which has the intension to use samples in a research study approved by the Swedish Ethical Review Authority, to a recipient. An MTA also regulates how samples are to be handled following the termination of the agreement, so that samples can no longer be used by the recipient for research or any other purpose.

An MTA can also be combined with a data processing agreement, which is always required when personal data is processed by someone other than the principal. This is to regulate processing of the sample's associated coded personal data (for example, the sample ID). A data processing agreement is a written agreement between a personal data controller and personal data processor. The agreement entails that the personal data processor may only process personal data in accordance with instructions from the personal data controller, and the personal data processor must undertake the same necessary security measures as the personal data controller. It is the responsibility of the personal data controller to ensure that such an agreement exists.

In order to allow the transfer of samples (and associated coded personal data) to a third country. i.e., countries outside the EU/EEA, one of the following is required:

- That there is an adequate level of security in the recipient country (in accordance with the decision of the European Commission). For information regarding the countries in which the European Commission has ruled that there is an adequate security level, see www.imy.se.
- That suitable security measures are in place to ensure the protection of the data and rights of data subjects, such as standard agreement clauses approved by the European Commission or Binding Corporate Rules (BCR). An MTA with accompanying personal data processor agreement is a BCR.
- In special circumstances and individual cases, for example if the data subject has given explicit consent to the transfer after having received information about the risks of transfer that may arise when there is no decision on adequate security levels or suitable security measures.

Source: Biobank Sweden, The Swedish Authority for Privacy Protection's webpage