Upcoming legislation. Effective July 1, 2023.

Link to the upcoming legislation: [Biobankslag (2023:38) Svensk författningssamling 2023:2023:38 - Riksdagen (Swedish only)]

A new Biobank Act

– a summary

Biobank Sweden is not responsible for any errors in this material or for any damage that may be caused by such errors. If you find inaccuracies in the material, please report these to info@biobanksverige.se

1. The main amendments from a research perspective

a) Expanded scope.
The Act shall apply to samples collected, stored, or used for the defined purposes of the Act. Thus, the law is not directed towards biobanks per se.

b) The purposes determine the legal requirements
The new Act now emphasises that the purpose for which the samples are biobanked is the crucial factor, not as in the current Act which focuses on where samples are collected.

c) New exceptions are imposed
The Act now excludes the following: - samples intended to be destroyed within nine months, - samples that have been substantially modified in the course of research or product production, - samples treated for transfusion, transplantation and IVF, and - samples to be included in medicinal products or medical devices.

d) Removal of secondary biobanks
The previous distinction between primary and secondary biobanks is considered too complex and an unnecessary administrative burden. In cases where samples are collected for research purposes, the research principal can be the biobank principal directly, even if the samples are collected within the healthcare system.

e) New rules for access to samples
Samples may only be released to legal entities. Access can be given through 1.) a release, 2.) samples being sent for use (e.g. analysis), or 3.) sample collection or biobank being transferred.

f) Removal of general subsidiarity
Deviating provisions in other legislation shall not take precedence over the new Biobank Act. In cases where other legislation shall take precedence over certain provisions of the Biobank Act, this must be stated directly in the relevant provision.

g) Samples may be stored abroad
If required for the purpose of the processing, samples sent abroad for certain use (e.g. analysis) may also be kept abroad.

h) More explicit rules on de-identification
De-identification may not be used as a substitute for consent. De-identification instead of destruction of samples may only take place under specifically regulated conditions.

i) New rules on penalties, damages, and supervision
New penal provisions will be imposed, and damages will no longer be adjustable. The Health and Social Care Inspectorate (IVO) will have a more limited mandate and will, for example, no longer review appeals over certain decisions.

j) Simplified definitions and clarified responsibilities
De-identification, biobank, principal, sample, and sample collection are concepts that will be given new, clearer definitions. Additionally, the respective responsibilities of the principal and the biobank custodian will be clarified.

2. Selection of provisions that are the same or almost the same as current provisions (Biobank Act and regulation)

a) The purpose of the Act remains the same
The new Act, like the current one, will regulate how identifiable human biological material (samples), may be collected, stored, and used for certain purposes while respecting the integrity of individuals.

b) Only identifiable samples are covered
The application of the Act requires that the samples are identifiable. The fact that a sample itself contains genetic information is not sufficient for it to be considered identifiable. According to the Swedish Government, it is required that there is identifying personal data that can be linked to the sample.

c) An ethical review is required for research purposes
The main rule is that an approved ethics application is required to collect, use, and store samples for research purposes. However, there are some exceptions, see more below. An ethical review is required for each new purpose.

d) Consent for research continues to be regulated by the Ethical Review Act
The consent rules in the Biobank Act shall not apply to the handling of samples for research purposes. As today, the Ethical Review Act will still govern information and consent requirements.

e) Health and Social Care Inspectorate (IVO) is the supervisory government agency
IVO continues to have supervisory responsibilities and decisions to establish a biobank must be reported to their register. However, certain information is removed from their mandate, such as approving the closure of a biobank and reviewing decisions on the release of samples.

f) A basic assumption is that samples released shall be coded
However, this does not apply if the coding prevents the purpose of the release. More detailed provisions on, for example, the storage of code keys will be removed from the act and must instead be communicated in a decree or regulation.

g) The interdependence on the GDPR and related legislation remains
The Biobank Act aims primarily to regulate the handling of samples, but since the provisions also lead to certain processing of personal data, a reference to the data protection legislation is needed.

h) Requirements for the storage of samples
As now, samples in a biobank must be stored in such a way that they do not risk being destroyed, while making sure unauthorized persons do not have access to them.

i) Obligation to destroy a sample is moved from regulation to law
This means that a new provision is introduced in the Act, stating that a sample, which due to provisions in law or other regulations may no longer be saved in a biobank, must be destroyed or, if this is not possible, de-identified under the responsibility of the biobank custodian.

3. Other amendments of interest

a) Two new purposes are introduced for samples obtained in healthcare
Samples may now also be used for the purposes of "identifying a deceased" and "investigating patient injury". However, this only applies to samples collected for healthcare and treatment. Samples may only be used to identify the deceased when other possible means have been exhausted.

b) Clearer rules on the information to be provided to donors
Among other things, donors must receive information about the purpose of the sample collection and what the sample may be used for. The Act does not set out any formal requirements for how the information is to be provided.

c) Consent to collect and store samples in healthcare are no longer required if the patient consents to the care
If certain information has been given, the consent to collect and store samples, needed for care and treatment, is included in the patient's consent to receive medical care.

d) Samples may be collected and stored for non-consensual treatment in certain cases
This shall apply if the donor is unable to take a position on the issue of collection and saving due to so-called incapacity for decision-making. In the same way as for minors as described above, this provision is allowed to only for care purposes.

e) The Act shall have retroactive effect
The Act will be applied to existing samples as well. This means, among other things, that samples collected within healthcare before the Act was brought into force, are also covered by the new purposes as described above. New consent is not required to continue processing the samples, provided that they are not to be used for a new purpose than that they were collected for originally.

f) The National Board of Health and Welfare may issue more regulations
The National Board of Health and Welfare may issue further regulations regarding information and consent, coding, and traceability, as well as for the reduction of samples in biobanks.