

ACT RELATING TO BIOBANKS

Chapter 1. Purpose of the Act, definitions and scope

§ 1. Purpose

The purpose of this Act is to ensure that the collection, storage, processing and destruction of material that forms part of a biobank are carried out in an ethically sound manner, and that biobanks are used for the benefit of individual people and of society as a whole. These activities shall take place in accordance with fundamental respect for the right to privacy and the principles of respect for human dignity, human rights and personal integrity, and without any discrimination of individuals from whom the biological material originates.

This Act shall ensure that material in a biobank can be used for health-related purposes, including diagnosis, treatment, research and teaching, in a way that meets satisfactory ethical standards.

§ 2. Definitions

The terms diagnostic biobank and treatment biobank as used in this Act mean a collection of human biological material contributed for the purpose of medical examination, diagnosis and treatment.

The term research biobank as used in this Act means a collection of human biological material and data obtained directly by the analysis of this material, and that is used or is to be used for research purposes.

The term human biological material as used in this Act means organs, parts of organs, cells and tissue and parts of such material obtained from human beings, alive or deceased.

The term donor as used in this Act means a person who provides biological material for inclusion in a diagnostic, treatment or research biobank.

§ 3 Scope

This Act applies to the collection, storage, processing and destruction of human biological material and information that forms part of a biobank, including the organisation of these activities.

Unless otherwise provided by this Act, health data and personal data derived from human biological material shall be processed in accordance with the provisions of the Personal Data Act, the Personal Health Data Filing System Act, the Health Personnel Act and any other legislation that specifically regulates the protection of personal data.

Biological material that is taken for the purpose of medical examination, diagnosis and treatment and that is destroyed shortly afterwards does not come within the scope of this Act. The Act nevertheless applies if such material is used for research purposes.

This Act applies in Svalbard and on Jan Mayen to the extent decided by the King. The King may lay down further rules to take account of local circumstances, including rules that depart from the provisions of this Act.

Chapter 2. Notification and organisation of biobanks

§ 4 Notification of the establishment of research biobanks

A research biobank may only be established after the matter has been evaluated by a regional committee for medical research ethics. Any person who wishes to establish a research biobank shall send notification to the Ministry, indicating whether the committee has recommended the establishment of the biobank or advised against it. The notification shall also include information on the following:

1. the purpose for which the biobank is to be established,
2. the type of material it is to contain and how the material is to be collected,
3. which population group and how many people material has been or is to be collected from,
4. how consent is to be obtained and what information donors will be given in advance,
5. the length of time for which the biobank is to be maintained and what will be done with the material when it is closed down,
6. the security measures related to operation of the biobank,
7. the person in charge of the biobank pursuant to section 7 and the data controller or controller pursuant to the Personal Health Data Filing System Act or the Personal Data Act,
8. how the biobank is to be financed and whether any financial gain will be made from the material in the biobank.

The Ministry shall give considerable weight to the recommendations of the regional committee for medical research ethics. If ethical considerations or important social interests so require, the Ministry may on the basis of the information provided in the notification decide that the biobank may not be established. If the Ministry does not object to the establishment of a biobank within 45 days after receiving such notification, its establishment is considered to be lawful.

New notification must be given to the Ministry if the scope of a biobank's activities falls outside that described pursuant to the first paragraph in the original notification.

The Ministry may by regulations lay down further provisions on the type of information that is to be provided pursuant to the first paragraph.

§ 5 Notification of the establishment of diagnostic biobanks and treatment biobanks

The Ministry shall be notified of any biobank established for the purpose of diagnosis and treatment. The notification shall include information on the matters listed in section 4, first paragraph, items 1-8. Such notification shall be sent to the Ministry within two months of the establishment of the biobank.

Section 4 applies if material from a biobank established for the purpose of diagnosis and treatment is to be used for research.

§ 6 Register of biobanks

The Ministry is responsible for maintaining a register of the biobanks for which it has received notification. The register shall be available to the public.

§ 7 Person in charge of a biobank

A person with higher medical or biological qualifications shall be in charge of each biobank. If the biobank contains data that can be linked to a natural person, it will also have a data controller pursuant to the Personal Health Data Filing System Act or a controller pursuant to the Personal Data Act. The controller or data controller shall appoint the person in charge of the biobank. The Ministry may decide that in certain cases, there shall be a board in addition to a person in charge of a biobank.

The person in charge of a biobank and the board shall ensure that it is established and managed in accordance with this Act and other legislation.

The Ministry may by regulations lay down further provisions on which biobanks require a board, the board's tasks, its composition, etc.

§ 8. Closure of biobanks and destruction of material

Any person who wishes to close down a biobank or to destroy some or all of the material held in a biobank shall notify the Ministry of this, or follow the procedures for closure or destruction that have previously been drawn up and notified to the Ministry.

The notification shall indicate the procedures to be followed in closing down the biobank or destroying the material.

If the Ministry does not object or ask for further information within 45 days of receiving such notification, the biobank may be closed or part or all of the material may be destroyed in accordance with the notification. If the Ministry decides that, given its contents, the biobank should not be closed or the material destroyed, it may decide that the biobank is to be maintained or that the material is to be transferred to another biobank. In such cases, the Ministry must take over the financial responsibility and ensure that the biobank is maintained and managed in accordance with this Act.

§ 9. Requirements relating to storage

The material in a biobank shall be stored securely and in accordance with the provisions set out in or laid down pursuant to the legislation. It shall also be stored in a way that shows respect for the donors of the material.

The Ministry may by regulations lay down further provisions on how human biological material and information in a biobank is to be stored.

§ 10. Transfer to another country

A biobank or parts of a biobank may only be transferred to another country with the approval of the Ministry and in accordance with the consent given by the donor of the material. The Ministry may lay down conditions requiring the material to be destroyed or returned after use.

The requirement for approval from the Ministry does not apply if material is transferred to another country in connection with the provision of health care for an individual person.

The Ministry may by regulations make exceptions from the requirement for the Ministry's approval for the transfer of samples and data that are part of ordinary international cooperation.

The Ministry may lay down regulations relating to the use of material from other countries for research purposes in Norway.

Chapter 3. Information and consent

§ 11. Provisions on consent for diagnostic biobanks and treatment biobanks

The provisions on consent to health care set out in sections 4-1 and 4-2 of the Patients' Rights Act also apply to the collection, storage and processing of human biological material, including the use of such material for prophylactic purposes, quality control and methodological developments.

For persons who do not have the capacity to grant consent pursuant to section 4-3 of the Patients' Rights Act, sections 4-4 to 4-8 of the same Act concerning consent on behalf of others apply correspondingly.

§ 12. Provisions on consent for research biobanks

Unless specific legal authority or another valid legal basis exists, the collection, storage and processing of human biological material for research purposes requires voluntary, express and informed consent by the donor. The same applies to the storage and use of data related to the biological material.

Documentation of consent shall be available, and it shall be based on information on purpose, methods, risks, discomfort, consequences and any other information of significance for the validity of the consent. The precise information required must be determined on the basis of an evaluation of risk factors, the sensitivity of the material, the vulnerability of the sample group, and so on.

The material in such a biobank may not be lent or disclosed to others or transferred to another country unless this follows from the consent given.

For the sampling of human biological material from a deceased person, the provisions of the Act relating to Transplants on presumed consent to autopsy apply correspondingly.

For persons who do not have the capacity to grant consent pursuant to section 4-3 of the Patients' Rights Act, sections 4-4, 4-5, 4-7 and 4-8 on consent to health care on behalf of others apply correspondingly to consent to the collection, storage and processing of biobank material for research purposes.

§ 13. Different, wider or new use of material and data

If previously collected material and data is to be put to different, wider or new use that does not fall within the scope of the original consent, new voluntary, express and informed consent shall be obtained.

In the event that it is impossible or very difficult to obtain new consent, the Ministry may grant an exemption from this requirement. In such cases, an assessment from a regional committee for medical research ethics shall be provided.

In cases involving the use of material and data from a deceased person, the presumed wishes of the deceased person and the sensitivity of the material shall be used as a basis for the Ministry's assessment. Proper respect shall be shown for the family and relatives of the deceased person.

Different, wider or new use of anonymised material does not require consent, but must be assessed by a regional committee for medical research ethics.

§ 14. Withdrawal of consent

Any person who has given their consent pursuant to sections 11-13 may withdraw such consent at any time.

If consent is withdrawn, the person who gave such consent may require the biological material to be destroyed. Similarly, the donor of the material in a research biobank may require that health and personal data collected together with the material or obtained by analysis or investigation of the material are erased or returned.

The right to withdraw consent or to require the destruction, erasure or return of material and data pursuant to the first or second paragraph does not apply if the material or data is anonymised, if the material forms part of another biological product after processing or if the data has already been used in scientific publications. Nor does the right to require destruction apply if it has been laid down in legislation that the material or data is to be stored.

§ 15. Access to material in a biobank for others

If the consent of the donor has been obtained in accordance with sections 11-13, others may be granted access to the biological material in a biobank or to specified parts of the material. Access may be given by making the material available on the premises of the person in charge of the biobank or by lending or disclosing the material to the person requesting it. The person who is requesting access to the material shall specify the purposes for which the material is to be used, how and for how long the material will be used, and whether the material will be destroyed, erased or returned after use.

In determining whether access to material is to be granted pursuant to the first paragraph, due consideration shall be given to whether such access will make the following difficult or impossible: the execution of statutory duties as regards storage and processing of the material by the person in charge of the biobank, safeguarding the interests of donors, or handling of the material by the person in charge and others in accordance with the purpose for which the

biobank was established. If the donor of the material has already entered a reservation against such access, this shall be respected.

If the person requesting access wishes to use the material for research purposes, a recommendation from a regional committee for medical research ethics shall be provided.

Access to material that makes it possible to identify the data subject may only be given if the recipient has a licence to process such material pursuant to the Personal Health Data Filing System Act or the Personal Data Act.

Payment may be required to cover the costs of providing others with access to the material in a biobank pursuant to this section.

If the person in charge of a biobank refuses a request for access to material, the decision may be appealed to the Ministry. The Ministry's decision is not subject to further appeal.

Chapter 4. Miscellaneous provisions

§ 16 Duty of confidentiality

The provisions of the Health Personnel Act relating to the duty of confidentiality apply correspondingly to all persons who establish, store material in, use or in other ways manage or work at biobanks.

§ 17 Control

Pursuant to the Act relating to the Public Inspection of Health Services, the Norwegian Board of Health shall be responsible for ensuring compliance with the provisions of this Act.

The Data Inspectorate shall ensure that personal data and personal health data derived from the material in a biobank are processed in accordance with the provisions of the Personal Data Act and the Personal Health Data Filing System Act.

§ 18. Penal measures

The Ministry may issue orders to a biobank or stop its further operation if it is being run in contravention of this Act or if the scope of its activities falls outside what has been notified to the Ministry in accordance with sections 4 and 5. The Ministry may take over operation of the biobank or require it to be closed down.

Any person who wilfully or through gross negligence collects, stores, processes or destroys material that forms part of a biobank in contravention of this Act is liable to fines or to a term of imprisonment not exceeding one year or both. Complicity is liable to the same penalties.

§ 19. Compensation and insurance

The controller or data controller and person in charge of a biobank pursuant to section 7 shall provide compensation for any damage that arises because a biobank has been operated in contravention of provisions laid down in or pursuant to this Act, unless it can be substantiated that the damage is not a result of errors or any failure on their part to perform their duties. The

compensation shall be equivalent to the financial loss the injured party has suffered as a result of contravention of the provisions of this Act. The controller or data controller and person in charge of the biobank may also be required to pay such compensation for non-pecuniary damage to the extent deemed reasonable.

The insurance cover taken out by private biobanks shall include security for the financial liability that may arise pursuant to the first paragraph.

The Ministry may by regulations lay down further provisions on the duty to have insurance cover.

Chapter 5. Entry into force, transitional provision, amendments to other acts

§ 20. Entry into force

This Act enters into force from the date decided by the King. The King may decide that different provisions shall enter into force on different dates.

[Entered into force on 1 July 2003 pursuant to Royal Decree of 23 May 2003]

§ 21 Transitional provisions

For biobanks to which this Act applies and that are already in operation when the Act enters into force, notification containing the information listed in section 4, first paragraph, items 1-8, shall be sent to the Ministry within two years of the entry into force of the Act.

§ 22 Amendments to other acts

Section 10b of the Act of 9 February 1973 No. 6 relating to transplantation, hospital autopsies and the donation of bodies, etc., shall be repealed.