



**[The Biobanks and Health Databanks Act]<sup>1)</sup>, No. 110/2000,  
as amended by Act No. 27/2008, 48/2009, 45/2014, 90/2018, 71/2019 and 99/2020.**

<sup>1)</sup> Act No. 45/2014, Article 21.

Where mention is made in this Act of ‘the minister’ or ‘the ministry’ without further definition, the reference intended is to the Minister of Health or to the Ministry of Health, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found [here](#).

**SECTION I  
General provisions.**

Article 1

*Objectives.*

The objective of the Act is to authorise the collection, keeping, handling and utilisation of human biological samples, [and keeping, handling and utilisation of health data which are acquired for scientific research]<sup>1)</sup> in such a way that confidentiality is ensured, that the interests of [individuals] are safeguarded and that the utilisation of [health information materials]<sup>1)</sup> serves the purposes of science and medicine, and is conducive to the public good.

The interests of science and of the community shall never be given priority over the interests of [individuals].<sup>1)</sup> It is prohibited to discriminate against [an individual]<sup>1)</sup> on the grounds of information derived from his/her biological sample [or health data].<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 1.

Article 2

*Scope.*

This Act apply to the collection of biological samples, and their keeping, handling, utilisation and storage in biobanks.

The Act does not apply to temporary keeping of biological samples taken for the purpose of clinical tests, handling, or for specific scientific study, provided such samples are destroyed when the test, treatment or research is completed. Temporary keeping means storage for up to five years, unless the National Bioethics Committee authorises a longer period of storage. Should the long-term preservation of such samples be desired, they shall be stored in a biobank.

[This Act apply to keeping, handling, utilisation and storage of health data in health databanks.

This Act apply to preservation of health data, which were acquired for scientific research in the health sector or arosed for such research, according to Act on Scientific Research in the Health Sector, after a study is completed. The Act does not apply to temporary keeping of health data for the purpose of specific scientific study, provided such information is destroyed when the research is completed.]<sup>1)</sup>

The Act do not apply to the storage of gametes and embryos under the provisions of [the Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research],<sup>2)</sup> to organs under the provisions of the Organ Removal Act, or to bodily remains under the National Heritage Act.

[The Health Records Act apply on handling of information in health records.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 2. <sup>2)</sup> Act No. 27/2008, Article 11.

### Article 3

#### *Definitions.*

In this Act the following terms have these meanings;

1. *Biological samples*: Organic material from a human being, alive or deceased, which may provide biological information about him/her.
- [2. *[Identifiable health information materials*: Health data which is possible to trace, directly or indirectly, to an individual.]<sup>1)</sup>
3. *Research samples*: Biological samples acquired for a scientific purpose.
4. *Clinical samples*: Biological samples taken for the purpose of health services to the individual.]<sup>2)</sup>
- [5.]<sup>2)</sup> *Biobank*: A collection of biological samples which are permanently preserved.
- [6. *Biobank of research samples*: A collection of research samples to be preserved for more than five years.
7. *Biobank of clinical samples*: A collection of clinical samples to be preserved for more than five years.]<sup>2)</sup>
- [8.]<sup>2)</sup> [*Scientific research in the health sector*: Research on human subjects, biological samples and health data in which scientific methods are applied in order to enhance knowledge of health and diseases.]<sup>1)</sup>
- [9.]<sup>2)</sup> *Clinical test*: Test carried out in order to provide health service to individuals.
- [10.]<sup>2)</sup> *Informed, free consent*: Consent granted in writing, of the person's own free will, after the donor of a biological sample has been informed of the purpose of taking the sample, its usefulness, risks attendant upon the process, and that the biological sample will be permanently preserved in a biobank for use under Article 9.
- [11.]<sup>2)</sup> ...<sup>3)</sup>
- [12.]<sup>2)</sup> *Donor of a biological sample*: An individual from whom a biological sample is taken.
- [13.]<sup>2)</sup> *Licensee*: Individual or legal entity granted a licence by the Minister to operate a biobank under Article 4 of this Act.
- [14. *Health data*: Information in health records, information and data from biobanks and health databanks, and other information on medical history and health.
15. *Health information materials*: Health data and biological samples.
16. *Health databank*: Databank which has been licensed by the Minister to store health data which are acquired for scientific research, or which arise from such research.
17. *Principal investigator*: Individual responsible for the implementation of the study in accordance with a research protocol which has been approved by the National Bioethics Committee or an institutional review board.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 3. <sup>2)</sup> Act No. 48/2009, Article 1. <sup>3)</sup> Act No. 99/2020, Article 1.

## SECTION II

### **[Establishment and operation of biobanks and health databanks.]<sup>1)</sup>**

<sup>1)</sup> Act No. 45/2014, Article 8.

#### Article 4

##### *Authority to establish and operate.*

[Establishment and operation of a biobank and a health databank, i.e. collection, keeping, handling, utilisation and storage of biological samples and health data which are acquired for scientific research, is only permissible to those who has been granted a licence by the Minister under this Act, having received

the opinion of the Medical Director of Health, the National Bioethics Committee and the Data Protection Authority.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 4.

## Article 5

### *Conditions of licence.*

A licence for the establishment and operation of a biobank [and health databank]<sup>1)</sup> is contingent upon the following conditions:

1. The terms of this Act, and government directives on the basis of the Act, shall be complied with.
2. [The databank]<sup>1)</sup> shall be located in Iceland.
3. The objectives of the operation of the biobank, and information on the operational basis of the bank, shall be clearly defined.
4. Conditions of storage for [health information materials]<sup>1)</sup> shall be explained.
5. Protocols of [the databank]<sup>1)</sup> shall have been drawn up, including rules of the biobank on arrangements for collaboration with foreign parties.
6. A governing board shall be nominated, *cf.* Article 6, and one individual shall be nominated to be responsible for [the biobank].<sup>1)</sup>
7. [The responsible party for the biobank and the health databank shall have necessary expertise and shall have practised independent research and development work within the health sector.]<sup>1)</sup>
- [8. If both scientific samples and clinical samples are in the same biobank, they shall be clearly separated and labelled in such a way as to ensure that their keeping, handling and utilisation is in accordance with the provisions of the Act and government directives issued on the basis of the Act.]<sup>2)</sup>
- [9.]<sup>2)</sup> [The evaluation of security and security measures, in gathering and handling of biological samples, shall be consistent with the rules<sup>3)</sup> laid down by the Data Protection Authority on security of personal data in biobanks and health databanks.]<sup>1)</sup>

The Minister may impose further conditions for the licence.

<sup>1)</sup> Act No. 45/2014, Article 5. <sup>2)</sup> Act No. 48/2009, Article 2. <sup>3)</sup> Regulation No. 660/2019, *cf.* 921/2019. Regulation No. 920/2019.

## Article 6

### *[Board of a biobank and health databank.]<sup>1)</sup>*

The licensee shall appoint a board of at least three people for each biobank [and each health databank]<sup>1)</sup>, which shall monitor its operation, [*cf.* however Article 6 a].<sup>1)</sup> The board is under an obligation to keep the Medical Director of Health, the Data Protection Authority and the National Bioethics Committee informed regarding [health information materials]<sup>1)</sup> and operations of [the biobanks].<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 6.

### [Article 6 a

#### *Authorisation to joint operation of a biobank and a health databank.*

The Minister may, having elicited the opinion of the Medical Director of Health, the National Bioethics Committee and the Data Protection Authority, grant permission to operate side by side biobank and health databank under one governing board, *cf.* Article 6.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 7.

## SECTION III

### **[Collection, handling and access to health information materials.]<sup>1)</sup>**

<sup>1)</sup> Act No. 45/2014, Article 15.

## Article 7

### *Consent of donor of a biological sample and revocation of consent.*

When a biological sample is collected for preservation in [a biobank of research samples],<sup>1)</sup> the free, informed consent of the person giving the biological sample shall be sought. This consent shall be given freely and in writing after the donor of a biological sample has been informed of the objective of the sample collection, the benefits, risks associated with its collection, and that the biological sample will be permanently stored at [a biobank of research samples]<sup>1)</sup> for use under Article 9. In addition the provisions of Article 20 of the Act on Protection of Privacy as regards [the Act on Data Protection and the Processing of Personal Data]<sup>2)</sup> shall be observed where applicable.

A donor of a biological sample can at any time withdraw his/her consent under paragraph 1, and the biological sample shall then be destroyed. Material that has been produced from a biological sample by performance of a research or the results of researches already carried out shall, however, not be destroyed.

[Biological samples may be taken for the purpose of clinical tests and shall be stored in biobank of clinical samples for use according to Article 9, provided that general information on this is mentioned by a healthcare practitioner or health facility.]<sup>3)</sup>

A donor of a biological sample may at any time [demand that his/her biological sample to be not stored]<sup>3)</sup> in [a biobank of clinical samples]<sup>1)</sup> for use under Article 9, in which case it shall thereafter only be used in the interests of the donor of the biological sample or by his/her specific permission, *cf.* however [paragraph 6 of Article 9.]<sup>4)</sup> [The demand]<sup>3)</sup> of a donor of a biological sample may apply to all [personally-identifiable]<sup>1)</sup> biological samples which have been taken or may be taken from him/her. Such [demand]<sup>3)</sup> must be complied with. The donor of a biological sample shall inform the Medical Director of Health of his/her [demand]<sup>3)</sup>. The Medical Director of Health shall be responsible for preparation of forms for giving such notice, and shall ensure that these are available at health institutions, and at the premises of self-employed health care professionals. [The Medical Director of Health shall maintain an encrypted register of individuals who have prohibited use of biological samples from clinical tests for scientific researches, and storage of such samples in a biobank of research samples. The register shall be accessible to the responsible parties of biobanks, who shall ensure that the individual's wishes are respected.]<sup>1)</sup> [Staff of the Medical Directorate of Health who carry out this work are subject to obligation of confidentiality according to Section X of the Administration Procedures Act.]<sup>5)</sup>

<sup>1)</sup> Act No. 48/2009, Article 3. <sup>2)</sup> Act No. 90/2018, Article 54. <sup>3)</sup> Act No. 99/2020, Article 2. <sup>4)</sup> Act No. 45/2014, Article 9. <sup>5)</sup> Act No. 71/2019, Article 5.

#### [Article 7 a

##### *Authorisation for storage of health data.*

On authorisation for storage of health data, which is acquired for scientific research or arise for such research, is subject to the Act on Scientific Research in the Health Sector.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 10.

#### [Article 7 b

##### *Agreements between the governing board and the responsible parties of scientific researches.*

The governing board shall make agreements to the responsible parties of scientific researches which deposits health information materials in a biobank. The agreement shall *inter alia* provide for storage and access to health information materials and how it shall be handled if the responsible party of a research is no longer able to fulfil his/her role.

The Minister may issue regulation on further implementation of this provision.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 10.

#### Article 8

##### *[Storage of health information materials.]<sup>1)</sup>*

[Biological samples shall be securely stored and labelled. Research samples [and health information materials]<sup>1)</sup> shall be stored without personal identification, and the connection between [them]<sup>1)</sup> and personal identification shall be in accordance with the rules of the Data Protection Authority.]<sup>2)</sup>

The storage of [health information materials]<sup>1)</sup> shall be stored in such a way that they are not lost or damaged, and that they are not accessible to unauthorised people.

[Health data from each scientific research shall be stored separately in a health databank. It is prohibited to link together health data on individuals from different researches while they are stored in a health databank.]<sup>1)</sup>

Should the licensee decide to cease operation of a biobank [or a health databank],<sup>1)</sup> or should the licence have been revoked under Article 14, the Minister shall, after receiving recommendations from the Medical Director of Health, the Data Protection Authority and the National Bioethics Committee, make a decision on the disposal of [the biobank],<sup>1)</sup> taking into account the wishes and proposals of the licensee.

<sup>1)</sup> Act No. 45/2014, Article 11. <sup>2)</sup> Act No. 48/2009, Article 4.

## Article 9

### *[Access to health information materials in biobanks and its use.]<sup>1)</sup>*

[Health information materials]<sup>1)</sup> shall be acquired for clearly defined and lawful purposes, and not used for other purposes, *cf.* however [paragraphs 2–7.]<sup>1)</sup>

The responsible party for [biobank]<sup>1)</sup> grants access to biological samples for further diagnosis of diseases. He/she may also grant access to biological samples for purposes of quality control, development of methods and tuition, provided that they are not personally identified.

[The governing board grants access to health information materials from a specific scientific research for further scientific researches, and the board shall adhere to the provisions of agreements made to the responsible parties of scientific researches, *cf.* provisions of Article 7 b.]<sup>1)</sup>

[It is not permitted to grant access to health information materials for scientific research unless a research protocol exists, which has been approved by the National Bioethics Committee or an institutional review board.]<sup>1)</sup>

[When access is granted to clinical samples for scientific researches, they shall be provided without personal identification. In exceptional circumstances it is permissible, with the approval of the Data Protection Authority, to provide biological samples with personal identification. The connection between biological samples and personal identification shall be in keeping with the rules of the Data Protection Authority.]<sup>2)</sup>

[The governing board of a biobank may, after receiving licence from the Data Protection Authority and the National Bioethics Committee as applicable, authorised the use of biological samples for other purposes than listed in paragraphs 2–4, provided that vital interests are at stake and the potential benefit outweighs any possible inconvenience to the donor of a biological sample or other parties.]<sup>1)</sup>

The Minister shall, having received proposals from the Medical Director of Health, the National Bioethics Committee and the Data Protection Authority, issue regulations<sup>3)</sup> making more detailed provision for the use of biological samples.

<sup>1)</sup> Act No. 45/2014, Article 12. <sup>2)</sup> Act No. 48/2009, Article 5. <sup>3)</sup> Regulation No. 1146/2010.

## Article 10

### *Right of disposal and fees.*

The licensee [of a biobank]<sup>1)</sup> is not deemed to be the owner of [health information materials]<sup>1)</sup>, but has right of disposal over them, with the limitations laid down by law, and is responsible for their handling being consistent with the provisions of this Act, and of government directives based on it. The licensee may thus not pass [health information materials]<sup>1)</sup> on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt.

The licensee may take a fee for [health information materials],<sup>1)</sup> or access to [health information materials]<sup>1)</sup>, equivalent to the cost of gathering, storage and access to [materials].<sup>1)</sup> Any further fee is prohibited.

A biological sample may be sent out of the country in the interests of the donor of a biological sample, for diagnosis or quality control. [Transfer of health information materials from Iceland is subject to the provisions of the Act on Data Protection and the [Processing]<sup>2)</sup> of Personal Data.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 13. <sup>2)</sup> Act No. 90/2018, Article 54.

Article 11  
*Confidentiality.*

All staff of biobanks [and health databanks]<sup>1)</sup> and those who have access to them, [including monitoring bodies],<sup>1)</sup> are subject to a duty of confidentiality regarding matters relating to their work which should be kept confidential, by law or by their nature. The obligation of confidentiality remains in force after employment, research or tuition ceases.

<sup>1)</sup> Act No. 45/2014, Article 14.

**SECTION IV**  
**Monitoring and duty to provide information.**

Article 12  
*Monitoring.*

The responsible party for [a biobank]<sup>1)</sup> shall be responsible for the implementation of internal monitoring, and that security assessments be carried out regularly, in accordance with the provisions of [the Act on Data Protection and the Processing of Personal Data].<sup>2)</sup>

The Data Protection Authority shall monitor the security of personal data in biobanks [and health databanks].<sup>1)</sup> The Data Protection Authority's monitoring of [biobanks]<sup>1)</sup> is subject to [the Act on Data Protection and the Processing of Personal Data].<sup>2)</sup>

[The Medical Director of Health monitors the operation of biobanks and health databanks. The implementation of the Medical Directors' of Health monitoring is subject to paragraphs 1 and 2 of Article 7 of the Medical Director of Health and Public Health Act, as applicable, *inter alia* on the authorisation of the Medical Director of Health to require information, data and access to institutions and companies for his/her monitoring role and apply measures according to paragraph 2 of Article 7, if he/she deems that the operation does not fulfil the terms of law and governments directives. The Minister may issue regulations on the further implementation on monitoring of the Medical Director of Health.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 16. <sup>2)</sup> Act No. 90/2018, Article 54.

Article 13

*[Duty of the government and the boards of biobanks to provide information.]<sup>1)</sup>*

The Medical Director of Health is under an obligation to promulgate in detail to the general public the terms of this Act on biobanks [and health databanks],<sup>1)</sup> especially the provision on [authorisation to take biological samples and store in biobank of clinical samples]<sup>2)</sup>, and also the rights of the individual under Article 7 and under paragraph 3 of this Article.

The Medical Director of Health shall annually issue a register of biobanks [and health databanks],<sup>1)</sup> their purposes, activities and protocols. The register shall contain *inter alia* information on the membership of the board of each bank, and the identity of the responsible party. This register shall be made public and shall be accessible to the general public.

[Governing board or the Medical Director of Health must provide an individual with information on whether health information materials, traceable to him/her, are stored in a bank and the nature of health information materials.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 17. <sup>2)</sup> Act No. 99/2020, Article 3.

**[SECTION IV A**  
**Search databases.]<sup>1)</sup>**

<sup>1)</sup> Act No. 45/2014, Article 18.

Article 13 a

Health care facility, operated by the state or local government, is authorised to manage search database for the purpose to explore the desirability of scientific research in the health sector. The managing director of the facility shall be the responsible party of the search database.

To a search database may be collected information from health records of the facility in question, which may be used to explore the desirability of scientific research. Information on where to get further data or biological samples, may also be entered to the database.

The information shall be preserved in access controlled search database in encrypted form in order to It be impossible to trace information to an individual without access key.

The responsible party of a search database shall set rules on daily operation of the search database, including on access control and access restrictions. The responsible party appoints a board of the search database, comprising three members. It shall be ensured that the board includes individuals with expertise in health sciences, ethics and computer science. The board receives requests from scientists, which request answers to questions from search database or access to it, and takes a stand to these requests.

It shall be ensured that an answer to a request from a search database is always anonymised. It is only authorised to grant statistical information, which may apply to a group of individuals, from a search database. Diagnosis and medical treatments shall be encoded. Information about less than ten individuals shall never be granted from a search database.

Results from a request of a search database may only be used for research after receiving licence from the National Bioethics Committee or an institutional review board. Results from a search database is unauthorised to publish officially.

Health care facility, which intends to manage search database, shall carry out the preparation of access key which shall be preserved on the responsibility of the Data Protection Authority. The access key may only be used to decode personal identification when the licence from the National Bioethics Committee or an institutional review board is prepared.

Establishment and operation of search databases is only authorised to those who have been granted a licence by the Minister, having received the opinion of the National Bioethics Committee and the Data Protection Authority.

A licence for the establishment and operation of a search database is contingent upon the following conditions:

1. The terms of act and government directives on search databases shall be complied with.
2. The search database shall be located in Iceland.
3. The objectives of the operation of the search database, and information on the operational basis of the bank, shall be clearly defined.
4. Conditions of storage for data in search database shall be explained.
5. Conditions of access to search database shall be explained.
6. The evaluation of security and security measures, in transferring and handling of data in search database, shall be consistent with the Act on Data Protection and [the Processing]<sup>1)</sup> of Personal Data.

The Minister may impose further conditions for the licence.

The Data Protection Authority shall monitor the security of personal data in search database.

The licensee may take a fee, equivalent to the cost of processing requests and delivering information from a search database.

The Minister may issue regulation on further implementation of this provision.]<sup>2)</sup>

<sup>1)</sup> Act No. 90/2018, Article 54. <sup>2)</sup> Act No. 45/2014, Article 18.

## **SECTION V**

### **Penalties.**

#### **Article 14**

The Minister may revoke the licence under the terms of this Act, if the licensee or its employees violate the terms of the Act or government directives on the basis of the Act, if the conditions of the licence are not fulfilled, or if the licensee proves unable to operate the biobank. Should the licensee violate the terms of this legislation or not comply with the conditions of the licence, the Minister shall give the licensee a written warning, allowing a reasonable period of grace to rectify matters. Should the licensee not comply with such a warning, the licence shall be revoked. In the case of deliberate violation or gross negligence, the Minister may revoke the licence without notice and without allowing time for rectification.

## Article 15

Violation of the terms of this Act and government directives based on it entails fines or imprisonment for up to three years, unless a more severe penalty is prescribed in other legislation.

A legal entity, as well as an individual, may be sentenced to pay fines due to violation of this Act. A legal entity may be fined whether or not the guilt of an employee of the legal entity has been proved. Should a member of the staff of the legal entity violate the terms of this Act or of government directives based on it, the legal entity may also be fined. The legal entity shall be responsible for payment of a fine imposed upon a member of its staff for violation of the terms of this Act, provided that the offence is connected to the employee's work for the legal entity.

## **SECTION VI** **Various provisions.**

### Article 16

*Government directives.*

The Minister may issue regulations<sup>1)</sup> on the further implementation of this Act.

The Minister shall issue regulations on how information on [authorisation to take biological samples and store in biobank of clinical samples]<sup>2)</sup> under paragraph 3 of Article 7 shall be provided, on how to ensure that [the demand of the donor of a biological sample]<sup>2)</sup> under paragraph 4 of Article 7 is complied with, on the register of those opting out, and its form, *cf.* paragraph 4 of Article 7, and how to ensure equal treatment of those who request access to biobanks [and health databanks]<sup>3)</sup> for purposes of scientific studies [under Article 9.]<sup>3)</sup>

<sup>1)</sup> Regulation No. 1146/2010. <sup>2)</sup> Act No. 99/2020, Article 5. <sup>3)</sup> Act No. 45/2014, Article 19.

### Article 17

*Entry into force.*

This Act shall take force on 1 January 2001.

## **Temporary Provisions.**

1. Before the Act comes into force, the Ministry of Health and Social Security shall assign the Directorate of Health to carry out thorough publicity among the general public on biobanks and regulations applying to collection and utilisation of biological samples.
2. Biological samples acquired before this Act came into force may be stored in a biobank, unless the donor of a biological sample declares his/her opposition to this. Otherwise the provisions of the Act shall apply to the storage, handling and utilisation of such biological samples.
- [3. Before 1 January 2015 the Ministry shall assign the Directorate of Health to carry out thorough publicity among the general public on biobanks, health databanks and regulations applying to collection, preservation and utilisation of health data.]<sup>1)</sup>
4. Health data, acquired for scientific research on human subjects before 1 January 2015, may be stored in a health databank, provided that the participant has granted his consent for storage of the data to use in later researches.

In case of scientific research on human subjects, where consent in writing or data research does not exist, the National Bioethics Committee may authorise that such health data shall be stored in health databank, unless the person which the data result from, is against it. Otherwise the provisions of the Act shall apply to the storage, handling and utilisation of such health data.]<sup>1)</sup>

<sup>1)</sup> Act No. 45/2014, Article 20.

*[This translation is published for information only.*

*The original Icelandic text is published in the Law Gazette.*

*In case of a possible discrepancy, the original Icelandic text applies.]*