



HELSINGIN BIOPANKKI
HELSINGFORS BIOBANK
HELSINKI BIOBANK

Helsinki Biobank
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www.helsinki-biobank.fi
Tel. 050 421 7659

Helsinki Biobank's information form for sample donors

This leaflet provides information regarding operations of Helsinki Biobank and the implications of becoming a biobank donor.

Summary

- Helsinki Biobank collects human biological samples and information for medical research and product development.
- Donating samples to the biobank is voluntary and based on consent. Refusing consent or withdrawing it later does not affect the availability of healthcare services.
- As a donor, you have the right to:
 1. Give a biobank consent
 2. Withdraw a given consent
 3. Be informed in which studies your samples and information have been used in
 4. Object to processing of your personal data
 5. Restrict processing of your personal data
 6. Request rectification of your data
 7. Request erasure of your data from the biobank (*'right to be forgotten'*)
- To exercise your above-mentioned rights, you may utilize forms provided by Helsinki Biobank.
- Your biobank consent may also apply to previously collected samples and information. Samples from legacy collections can also be transferred to the biobank by announcing the planned transfer e.g. in the media or by letter. You can at any time object the transfer of your samples and information to the biobank.
- The biobank grants access to samples and associated data to research with emphasis on protecting the donor's privacy. Biobank operation is governed by the Finnish Biobank act and EU General Data Protection Regulation.
- The biobank may store samples and information for the time being. However, the biobank is required to evaluate every 10 years whether storage is still justified, and discard samples and data if this is not the case.
- The biobank is responsible for ensuring that any processing or subsequent use of your information is not in conflict with the legal bases for processing personal data.

What is biobank research?

The Finnish biobanks store and process human biological samples and information for the purpose of providing them for future medical research and product development. The biobank operation is governed by the Finnish Biobank Act (688/2012) and supervised by the National Supervisory Authority for Welfare and Health (Valvira) and the Finnish data protection authorities.

The processing of samples and related personal data is based on the donor's consent, as defined by the Finnish Biobank Act. The EU General Data Protection Regulation (GDPR) also provides legal rationale for processing samples and data. In addition to consent, these legal grounds include substantial public interest, especially in the areas of public health, and scientific research purposes. Research and data processing can be conducted by Finnish and international universities, research institutes and companies. Your samples and information can only be released to projects approved by an independent ethical committee. The ethical committees ensure that processing of the samples and information is appropriate and in line with the operations of a biobank, legal protection of the sample donor and the data protection legislation.

Biobank research is aimed at finding out causes of diseases, and understanding the role of genetic factors, environment and lifestyle in their aetiology. It also aims at improving diagnostics and developing safer, more effective, as well as personalised treatments and ways to prevent disease. Biobank samples and associated information can be used in various research projects, including collaboration and product development projects, also outside of European





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Union. Researchers may be charged for the biobank's services. Data analysed from the samples is returned to the biobank and can be used for further research.

Helsinki Biobank

Helsinki Biobank was established by the Hospital District of Helsinki and Uusimaa (HUS), the University of Helsinki, Kymenlaakso Social and Health Services (Carea) and the South Karelia Social and Health Care District (Eksote) to support patient care and medical research in these regions. Helsinki Biobank is owned by and operates within HUS, which is responsible for storing the samples and information. Fields of biobank research cover promotion of public health, investigation and prevention of underlying causes of disease, as well as development of related products and treatment practices.

Operations of the biobank and processing of samples and personal data is based on the Biobank Act (688/2012, Section 5) and EU General Data Protection Regulation, Article 6(1) (a) and (e), Article 9(2) (a), (g), (i) and (j).

Samples and information in the biobank

Biobank samples may be collected as part of normal healthcare procedures, as part of a scientific study, or specifically for biobank use. This processing is based on the Biobank Act, Section 13. Previously collected samples can also be transferred to the biobank. The most commonly collected sample is blood, but also other samples can be collected, such as tissue (biopsy sample; fine needle, bone marrow or exfoliative cytology sample, or some other tissue removed in surgery), secretion (urine, saliva, sputum), or DNA or cells isolated from a sample. Information about the sample and the donor, such as gender, health information (diagnoses, medical procedures, treatment, results of laboratory and other examinations, imaging data), sample type, sample date, processing history, research information (results of biobank research) and information about the individual's genome (genes) can be associated with the samples.

Information related to samples and the sample donor can be obtained from the donors themselves, from electronic health records, other biobanks, national social and healthcare registers (e.g. THL's Care Register for Health Care, Cancer Registry), Statistics Finland, Population Register Centre or from the registers of the Social Insurance Institution of Finland (e.g. Kela's register of higher special reimbursements for medicines), and from the material collected by research projects.

Genetic heritage and how it affects health and disease can be examined from the biobank samples. The use of genetic information is increasingly important in the study of development mechanisms of diseases and in daily diagnoses. It is also possible to map the entire genome, i.e. the hereditary material, of an individual.

The biobank processes the samples and information in accordance with data security requirements for confidential data. Data protection is secured by encoding the samples and by drawing up detailed agreements on their use. The samples and related personal data are processed by the biobank personnel. In addition, various scientific research projects conducted in Finland and abroad, also outside the EU, may apply for samples from Helsinki Biobank. These research projects must be approved by a Finnish ethical committee before applying. The samples and information are processed by researchers and research assistants. Research results and genome data can be shared with researchers through international databanks without sharing personal identification details, so identifying an individual person is almost impossible.

Specific requirements need to be met before samples and personal data can be released outside the EU. For instance, a non-EU country or its area or a certain sector (e.g. pharmaceutical industry) can be judged by the European Commission to meet a similar level of data protection requirements as the EU countries. Without such a status, information can only be released if the non-EU country has approved and committed to EU's standard data protection terms and conditions through a separate agreement. Operators based in the United States can also be included in the so-called Privacy Shield list, provided that they have demonstrated adequate protection of personal data. In other words, strict additional terms apply to the processing of personal data outside the EU. You have the right to know if your information has been transferred outside the EU. If your information is transferred outside the EU, you have the right to know what kind of safeguards were used.





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You have the right to receive information

You can request Helsinki Biobank for information on whether or not your samples or associated information are stored in the biobank. You are also entitled to know grounds for storing your samples and information (consent or notification procedure in the case of old samples), from where your data was obtained from, and who has been granted access to your samples and information.

You have the right to receive this information free of charge and within a reasonable period (within one month of the request). This period may be extended by two (2) further months if your information request is extensive or the collection of the information is very complex for a justified reason. You will be informed of any such extension, together with the reasons for the delay. Written information will be provided on paper, but data can also be requested in electronic format. The information may also be provided orally, provided that your identity can be reliably verified.

You also have the right to request any information about your health status that has been obtained in biobank research. However, it is seldom possible to benefit from the biobank's research results directly in your own healthcare. If you wish, you can request analysis over the meaning of the results analysed from your samples, but a fee may be charged to cover the costs of the result verification and analysis.

The data controller of Helsinki Biobank is HUS (the Hospital District of Helsinki and Uusimaa, Stenbäckinkatu 9, PO Box 100, 00029 HUS, Business ID: 1567535-0). In data protection matters, please contact the Biobank office first: biopankki@hus.fi. You can also contact the Data Protection Officer of HUS: eutietosuoja@hus.fi.

Possible requests for participation in further research projects and contact requests

When you decide to become a biobank donor, we ask you in the consent form whether we may contact you if significant information regarding your health status is revealed in a research project, such as a serious risk of a disease for which there is effective treatment and the effects of which can be prevented. The biobank will not provide subsequent treatment but can direct you to healthcare services if necessary. We also ask for a permission to enquire whether you would like to participate in a research project or sample collection that is not covered by this consent, e.g. to take part in a clinical trial or give a new sample.

Samples and information can be stored in the biobank for the time being. However, the biobank is required to assess regularly, at least every 10 years, whether storing of the samples and information is still justified. Only information and samples necessary for research will be stored, otherwise they must be disposed.

Potential benefits and drawbacks of biobank activities to the sample donor

In most cases the donor's personal healthcare does not benefit from donating samples and information to biobank research as such. The aim of biobank research is to develop more effective treatment and disease prevention methods that benefit the entire population. Appropriate prerequisites for research are assessed in advance, so the risk of the samples and information in the biobank being misused is very low.

Biobank samples and related information cannot be used in criminal investigations, or in any decision making involving administrative, employment relationship or insurance agreement matters. Unauthorised use of biobank information or materials is a criminal offence.

Voluntary nature of the consent, withdrawal of the consent and your other rights

You have the right to:

- Give a voluntary biobank consent that is valid until further notice. Healthcare services are available to you regardless of whether you have given a biobank consent.
- Withdraw your consent at any time without giving a specific explanation. If you withdraw your consent, your information will no longer be utilized in new research. However, your samples and data will not necessarily be disposed of, since their storage may be necessary for limited purposes such as verifying the validity of studies already carried out.
- Object to i.e. prohibit processing of your personal data. This concerns the data generated and managed by Helsinki Biobank and covers the sample registry, consent registry and pseudonym registry. Your samples will not be included in possible transfers of legacy collections to the biobank.





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- Restrict processing of your samples and data.
- Request rectification of your data (e.g. if you notice a mistake or if any information is missing or inaccurate).
- Request erasure of your data ("right to be forgotten"). Data and material that has already been handed over to research projects, or the results generated in such projects, cannot be erased from records.
- Access your data and be informed in which studies your samples and data have been used. You can also inquire on what grounds your samples and data are stored in the biobank (prospective consent or notification process in the transfer of legacy collections) and where the data has been obtained from.

Should you wish to exercise your rights stated above, forms for doing so are available on the website of the Helsinki Biobank (www.helsinki-biobank.fi). Upon request, these forms can also be sent to you by post. Forms can be returned directly to the biobank or given to healthcare or research personnel. Biobank staff will be happy to provide further information.

Your consent is valid once you have signed it. Withdrawal of your consent as well as restrictions and objections to processing of your data enter into force once the biobank has received your notification. Your requests to erase or rectify your data will be handled immediately. Withdrawing your consent or restricting or objecting of processing of your data does not retrospectively affect the material to which biobank research has been granted access by the biobank before your notification.

Personal data about you may be collected for biobank research also indirectly. For scientific research purposes, information may be collected from medical records or other registries. In these cases, you have the same rights to access your information and to obtain information about on what grounds and for what purpose your information is processed, who processes your information and where your information has been obtained from. You also have the right to request that your personal data is rectified, erased or restricted. In addition, you have the right to file a complaint with the Data Protection Ombudsman. You have the right to receive information about the following: the data controller's name and contact information and the data protection officer's name and contact information. You also have the right to be notified if your data is transferred outside the EU and provided information about the necessary safeguards taken to protect it. If your information is processed automatically, you have the right to know how it is processed and what the possible risks and consequences are.

If you are unsatisfied with the use or processing of your information or if you have any questions, please contact the Helsinki Biobank (biopankki@hus.fi). You can also contact the Data Protection Officer of HUS (eutietosuoja@hus.fi).

Alternatively, you can contact the Office of the Data Protection Ombudsman, the authority that oversees implementation of data protection in Finland: (Office of the Data Protection Ombudsman, Ratapihantie 9, 6th floor, 00520 Helsinki; tietosuoja@om.fi).

In addition to the grounds for processing personal data laid down in the Biobank Act, processing of data is based on the regulations of the General Data Protection Regulation of the European Union, Article 6(1) (a) (consent) and (e) (processing is necessary for the performance of a task carried out in the public interest), Article 9(2) (a) (consent), (g) (processing is necessary for reasons of substantial public interest), (i) (processing is necessary for reasons of public interest in the area of public health) and (j) (processing is necessary for scientific research purposes). The Data Protection Regulation entered into force on 24 May 2016, and it has been applied from 25 May 2018. The Regulation grants several rights regarding the processing of your data and includes several obligations for the processor of the data, in this case the Helsinki Biobank and the Helsinki and Uusimaa Hospital District (HUS).

Helsinki Biobank has been registered by Valvira (National Supervisory Authority for Welfare and Health) in the biobank register since 21 April 2015 under number 005. The controller required under the Personal Data Act is the Helsinki and Uusimaa Hospital District, which is responsible for the lawful processing of personal information in connection with the biobank's activities. A description of the personal data file of Helsinki Biobank has been drawn up in accordance with Section 10 of the Personal Data Act. Should you wish to see the document, it can be made available to you.

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