



THL Biobank Information Leaflet for Biobank Sample Donors

We kindly request your permission that samples and information collected from you in connection with the FinHealth 2017 Study could be stored at THL Biobank and used for biobank research. Participation is voluntary and subject to consent, and you have the right to withdraw your consent at any time without providing a reason. If you do not give biobank consent or you choose to withdraw your consent later, you can still participate in the FinHealth 2017 Study. Below, we describe what biobanking is and explain what giving consent means.

Summary

- Human samples and information related to the samples and to the Sample Donor are stored in the biobank for medical research and development purposes. Provisions on biobanks and biobank research have been written in the Finnish Biobank Act (688/2012), where particular attention is given to the rights of the Sample Donors.
- Samples and related information are stored in the biobank for long periods of time, even decades. Researchers who are given access to samples and related information do not usually receive any personal identification details of the Sample Donors.
- Participation in biobank activity is voluntary and requires the Sample Donor's informed consent.
- The Sample Donor has the right to know which biobank research projects have been using his/her samples and related information.

THL Biobank and the purpose of biobank research

The purpose of biobanks is to create high-quality settings for medical research that are subject to supervision by the authorities, to discover why diseases develop and how genes, lifestyles and the environment affect the onset of diseases. Biobank research results may help in the prevention of diseases and in developing safer, more effective and more personalised treatments.

THL Biobank's activities support the statutory functions of the National Institute for Health and Welfare (THL). Samples stored in THL Biobank can be used in medical research that aims to promote population health, identify factors affecting the mechanisms of diseases, prevent diseases, or develop products and treatment practices that promote population health and well-being or are used in health care. The purpose of THL Biobank is to compile a significant resource of Finnish population-based samples and data for use in future research. Research into factors that affect health often requires extensive data sets as well as follow-up periods that can extend over several decades.

Samples and data stored in the biobank

Samples and data stored in the biobank include biological samples (e.g. blood samples, DNA, cells, saliva), information obtained directly from the sample donor (on lifestyle and diet, for example), measurements (e.g. blood pressure, height), test results (e.g. cholesterol level) and register data (e.g. hospital admissions, medication). Samples stored in THL Biobank can also be used to extract genetic information, and to study the effects of genetic factors on health status.

Samples may be linked to data obtained from patient registers, national social welfare and health care registers (e.g. Care Register for Health Care, Cancer Registry), Statistics Finland's registers, Kela's registers (e.g. Drug Reimbursement Registers) as well as from other biobanks. In order to link register data to biobank data, the biobank discloses the sample donor's personal identification number to the register controller who then links the sample donor's data in the register with the data obtained from the biobank. These data will be submitted to researchers in a coded form without personal identifiers. Register data can be used to acquire information about the effectiveness of treatments or about diseases that develop after the sample donation. These data can then be compared to the data stored in the biobank.

www.thl.fi/biobank

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Access to samples and information, and the benefits and risks of biobank research

The primary task of THL Biobank is to support medical research. Therefore, it is not expected that individual sample donors would gain any personal benefit from taking part in biobank research. The risk for misuse of samples and data stored in the biobank is extremely low. THL grants access to the samples and information stored in the biobank, and is responsible for privacy protection and securing confidentiality. Access to samples and information stored in the biobank can be granted to domestic and international research projects, including countries outside the EU and EEA (e.g. the United States) where the statutory level of privacy protection might be different. The privacy of individual sample donors is protected by allocating a coded identifier to samples and data, and by strict access agreements that define the terms and conditions for sample and data usage and handling. Full privacy protection is difficult to achieve in, e.g., genetic research, but in practice genetic information can be linked back to the sample donor only if the operator is already in possession of the sample donor's genetic and personal information from another source. Identifying an individual sample donor based on the coded information is next to impossible. Access rights are subject to the provisions of the law and to the consent given by the sample donor. THL Biobank does not sell the stored samples and related information to any third parties. However, it may charge the researcher a fee to compensate for work and expenses. The biobank's collaborative projects may result in commercial applications, such as new medications or treatments. Samples and data stored in the biobank cannot be used in criminal investigations, or in administrative, recruitment or insurance processes that involve the sample donor. Unauthorised use of biobank data is a criminal offence.

Requests for recontact

THL Biobank's Consent Form includes a request for permission to recontact you at a later date to acquire additional information or to take additional samples, for example. You are also asked to give permission to contact you if the analysis of the donated sample reveals important information related to your health that could be of benefit to you, such as a serious risk related to a drug or disease. Any results obtained in research laboratories must always be confirmed by an accredited health care laboratory using a fresh sample. You can decline consent to be contacted by the biobank.

Consent withdrawal and restrictions

Your consent is valid until further notice. You have the right to withdraw or alter your consent, or impose restrictions on the use of your samples and information at any time and without providing a reason, by sending a written notice to THL Biobank. After you have withdrawn your consent, access to your samples and information stored in the biobank is no longer granted. However, any ongoing studies that were initiated before your withdrawal may be completed. It may be necessary to temporarily store samples and information even after you have withdrawn your consent to verify, for example, the accuracy of the research results.

Right to receive Information

You have the right to receive, upon request, information on

- Whether or not samples taken from you or information related to you are stored in a biobank, and if yes, why;
- Where the stored information has been obtained from;
- Which and what type of research projects have been granted access to your samples and information; and
- Test results on your sample, and their significance. A fee might be charged for determining the significance of the test results. The fee shall not exceed the actual costs.

Where do I get more information?

For additional information on current biobank research, please visit THL Biobank's Web pages at www.thl.fi/biobank. These pages also include information on the organisation of THL Biobank, contact details, and instructions on how to receive information stored about you in the biobank.