INFORMATION FORM FOR BIOBANK SAMPLE DONORS

We ask for your consent to allow your samples and personal information to be collected in the FHRB Biobank and to be used in biobank research. This declaration provides information regarding operations of the FHRB Biobank and the implications of giving a consent.

Summary

- Human biological samples and information are collected to a biobank for medical research and product development purposes.
- Donating samples and information to the biobank is voluntary and based on consent. Refusing consent or withdrawing it later does not affect the availability of healthcare services.
- The consent may also apply to previously collected samples and information. They can be transferred to the biobank by announcing the planned transfer in the media or by letter so that the donor can object to the transfer and processing of his/her samples and information in the biobank. The sample donor has the right to know in which research projects his/her samples and information have been used.
- The biobank grants access to samples and the related information to research with emphasis on protecting the donor's privacy.
- The biobank may store donor's samples and information even for decades.

Biobank and the significance of biobank research

A biobank is a unit compliant with the Biobank Act (688/2012), supervised by a regulatory authority. A biobank collects and stores human biological samples and related information and can also release them for medical research and development projects. Biobank research aims to discover the causes of disease and methods of prevention, as well as to understand the role of genetic factors, environment and lifestyle in their etiology. The aim is to develop safer, more effective and more personalized treatments in addition to improving diagnostics. Samples and associated information can be used in various projects and commercial collaboration and product development projects also outside the European Union. Researchers may be charged for the biobank services. Research results are returned to the biobank for use in future projects.

FHRB Biobank

The FHRB Biobank was established and is owned by the Finnish Hematology Association, Finnish Red Cross Blood Service, and the Institute for Molecular Medicine Finland (FIMM). It is an infrastructure created to meet the needs of future hematological research. It serves research that benefits from biobank samples from this research area. The research area of the biobank comprises the prevention of hematological diseases, and includes diagnostics, care and follow-up.

The samples and information in the Biobank

Biobank samples can be collected as part of normal healthcare procedures, along with participation in a scientific study, or specifically for the biobank. Previously collected samples can also be transferred to the biobank. Samples may consist of, e.g. tissue (biopsy sample, fine needle, bone marrow or exfoliative cytology sample or some other tissue sample removed in surgery), blood, bodily fluids (urine, saliva, mucus) or DNA or cells isolated from samples. Information related to the sample and the donor are linked to the sample: e.g. gender, health information (diagnoses, medical procedures, treatment, laboratory- and other results, imaging records), sample type, time of collection, history of use, research data (results from the biobank research) and information about the individual genome (genes).

The related information to be linked with the samples and sample donor can be obtained directly from the donor, patient records, another biobank, national social and healthcare registers (e.g. the National Institute for Health and Welfare Care Register for Health Care, Cancer Registry), Statistics Finland's registers, Population Register Centre, or from the registers of the Social Security Institution's special reimbursement register (e.g. Kela's register of higher special reimbursements for medicines), as well as from the material collected by research projects.

The biobank samples can be used to examine the genetic heritage of an individual and how it affects health and disease. The use of genetic information in the study of development mechanisms of diseases and daily diagnoses is increasing extensively. Today, it is also possible to map the entire genome (i.e. the hereditary material) of an individual.

The FHRB Biobank is the owner of the samples and related information collected into it.

You have the right to receive information

You can approach the biobank for information on whether or not your samples or associated data are stored in the biobank. You can also request the grounds for storing your samples and information (consent or notification procedure in the case of old samples), from where your data was originated and for which purposes the biobank has granted access to your samples and information. Additionally, you can request the health related information determined in the biobank research. However, it is seldom possible to benefit from the biobank results directly in your own treatment. If you want to, 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.

Possible requests for participation in further research projects and contact requests

In the consent form, we ask you whether we may contact you if significant information regarding your health status is revealed in a research project, e.g. 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 when needed. We also ask for permission to enquire whether you would like to participate in a research project or sample collection not covered by this consent, e.g. to take part in a clinical trial or provide a new sample.

Benefits and drawbacks for the donor

Generally, no immediate benefits are to be expected regarding your treatment by granting the biobank consent to access samples and information. The aim of biobank research is to develop treatment that is generally more effective, together with disease prevention methods that benefit the entire population. Appropriate prerequisites for research projects are assessed in advance, so the risk for misuse of the samples and information in the biobank is minimal. All sample and information management complies with data security requirements for confidential data. Data protection is secured by encoding the samples and by drawing up detailed agreements on their use. When it comes to research done outside the EU, the data security level is managed by special contracts as the level of data security protection may be different there. Scientific results and genomic data can be shared with researchers through international databases without sharing personal identifiers, so identifying an individual person is almost impossible.

Biobank samples and related information are not allowed to be used in criminal investigation, in administrative decision-making, or in employment relationship or insurance agreement evaluation. Unauthorized use is a criminal offence.

Voluntary nature of the consent, withdrawal of consent and consent validity time

It is voluntary to give consent, and the consent is valid until further notice. Healthcare services are normally available to you regardless of whether you have issued biobank consent. You can withdraw your consent at any time and the content of it can also be restricted.

A consent, a withdrawal of consent, a restriction and an objection notification enter into force once the biobank has received your notification. Withdrawing your consent or restricting or objecting to it does not retrospectively affect the material to which biobank research has been granted access by the biobank before your notification. The withdrawal of consent does not always mean that the sample or personal information will be deleted from the biobank. Sometimes it is crucial to save the samples and other documentation in order to validate scientific results. You can give consent, withdraw it or restrict it or object the right to use your samples or information in writing by sending a signed form directly to the FHRB Biobank or by giving it to healthcare or research staff.

You can find more information about the biobank activity and contact persons and also the above-mentioned forms on our website (http://www.fhrb.fi/front-page.html). The forms can alternatively be sent to you by post. Biobank staff also gladly provide more information.

Contact information:

Finnish Red Cross Blood Service
FHRB Biobank
P.O.Box 2, 01731 Vantaa

Tel. 029 300 1010
fhrb@veripalvelu.fi, www.fhrb.fi

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