DECLARATION FOR BIOBANK SAMPLE DONORS

Using the attached consent and acceptance form, we ask you to give your consent to sample collection and the transfer of samples and associated data to the Finnish Hematology Registry and Clinical Biobank (the FHRB Biobank). The consent concerns samples collected from you in the future. We also ask you to consent to being notified of any clinically significant findings. In addition, we ask for your acceptance for your health-related data being attached to your sample, and for the release of this data to biobank research. Both your consent and your acceptance are required for the transfer of your samples and attached data to the Biobank. This Declaration describes the FHRB Biobank and what it means to provide your consent and acceptance. The information will be explained to you by a professional familiar with biobanking.

Summary

- The Biobank collects human samples and data for medical research and product development.
- Participation in biobanking is voluntary and is based on consent and acceptance. Declining to give consent and acceptance, withdrawal of consent, or objecting to the use of your data will not affect your right to receive healthcare services.
- Sample donors have the right to know which studies have used their samples and data.
- Donors have the right to object to the processing of their data.
- The Biobank releases samples and associated data for research purposes in a manner that protects donor privacy.
- Donor samples and data may be stored in the Biobank for up to decades.

The Biobank and the purpose of biobank research

The Biobank is a unit, as referred to in the Biobank Act (688/2012), that processes human samples and data and releases them for medical research and product development projects. It is overseen by the authorities. Biobank research helps understand medical conditions: their causes and ways to prevent them, and how genes, the environment and lifestyle influence their development. The purpose of biobank research is to develop treatments that are safer, more effective and more individualised, and to improve diagnostics. Samples and associated data can be used in multiple studies and commercial collaboration and product development projects, including outside the European Union. Researchers may be charged a fee for using the Biobank's services. The research results are returned to the Biobank for use in subsequent projects.

FHRB Biobank

The FHRB Biobank was founded and is owned by Suomen hematologiyhdistys ry (the Finnish Association of Hematology), the Finnish Red Cross Blood Service, and the Institute for Molecular Medicine Finland (FIMM) of the University of Helsinki. The FHRB Biobank was established to meet the needs of future hematological research that will benefit from biobank samples. The Biobank's research area includes the prevention, diagnosis, treatment, and monitoring of hematological diseases.

Biobank samples and data

Samples stored in the Biobank can be collected as part of treatment-related sample collection or participation in a scientific research study, or specifically for the Biobank. Sample types stored in the Biobank include tissue samples (biopsy, fine-needle aspiration and bone marrow samples, smears, and otherwise surgically removed tissue), blood samples, bodily fluid samples (urine, saliva, sputum), and DNA or cells from samples. Data about the sample and the donor and special categories of personal data are attached to the samples. These categories include gender, data concerning health (diagnoses, medical procedures, treatment, examination results including laboratory test results, imaging records), sample type, time of collection, processing history, study data (results of biobank research), and data concerning the donor's genetic information. The legal basis for the processing of personal data by the Biobank is public interest in the area of public health as referred to in the EU General Data Protection Regulation (GDPR, 2016/679, articles 6(1)e and 9(2)i).

Data to be associated with the samples and the donor can be collected from the donors themselves or from patient documents, other biobanks,

national healthcare and social welfare registries (such as the Finnish Institute for Health and Welfare's Care Register for Health Care or the Finnish Cancer Registry), Statistics Finland, the Finnish Digital and Population Data Services Agency or registries of the Social Insurance Institution of Finland (Kela; including Kela's register concerning special reimbursement for medicinal products), data sets collected by research projects, and from other sources. Such data can be collected and linked to the Biobank's samples and data when the Biobank's material is released for biobank research. The samples can be analysed for the donor's genetic information and its influence on morbidity. Using genetic information in research into the mechanisms leading to disease development and in everyday diagnostics is becoming much more common. Mapping a person's entire genome (the complete set of genetic information) has also become possible.The FHRB Biobank owns and is responsible for storing all the samples in the Biobank together with the associated data.

You have the right to receive information

You can ask the FHRB Biobank if we have stored samples collected from you and data concerning you, what the basis for storing them is (consent and acceptance, or notification procedure for older samples), from what sources we have collected your data and to which parties your samples and data have been released. You can also ask us what data concerning your health has been determined from your sample as part of biobank research. However, the results of biobank research are rarely directly applicable to your treatment. If you wish, you can request a clarification of what the results mean, but you may be charged a fee covering the costs of confirming and clarifying the results.

Requests for further studies and contacting you

In the consent and acceptance form, we ask you if we can contact you if research uncovers significant information relevant for your health, such as a serious risk of a medical condition for which there is an effective treatment or the effects of which can be prevented. The Biobank doesn't provide treatment, but where necessary directs donors to the appropriate healthcare services. We also ask for your specific consent to being contacted by us to ask whether or not you'd be willing to participate in a study or sample collection to which this consent doesn't apply. Such situations could include requests to participate in a research study or to provide a new sample.

Benefits and possible detriment to donors from biobanking

Providing samples and data for use in biobank research usually can't be expected to benefit you personally in relation to treatment. The goal is to find more effective treatments and means of disease prevention to benefit the general public. It is assessed beforehand that the studies will meet the appropriate requirements, which means that the risk of any abuse of Biobank samples and data is very low. The Biobank processes samples and data in compliance with the data security requirements for confidential data.

Data protection is ensured through sample coding and precise agreements for use. In non-European Union countries, where the standard of statutory data protection may vary, an appropriate standard of data protection is ensured through the use of special contracts. Research results and genomic data may only be disclosed to other researchers through international databases without personal identifiers, making it nearly impossible to identify an individual person.

Biobank samples and data may not be used in criminal investigations, any administrative decision-making concerning the donor, or for assessments related to an employment relationship or insurance contract. Unauthorised use constitutes a criminal offence.

Consent and acceptance: their voluntary nature, withdrawal and validity

Providing consent and acceptance is voluntary. You'll be able to use healthcare services as normal irrespective of whether or not you provide your consent and acceptance to biobanking. You can withdraw your consent before providing a sample, or at the latest before the sample and associated data are transferred to the Biobank. You can also object to the use of your data (see Exercising your right to object).

Your consent and acceptance, withdrawal of consent, and/or objection to data use take effect when the Biobank has received your notification. Consent and acceptance for the FHRB Biobank only concern the FHRB Biobank. If consent and acceptance are provided, they are valid until further notice.

You can withdraw your consent and/or object to the use of your samples and data in writing by submitting a signed Biobank refusal form directly to the FHRB Biobank or by giving it to healthcare or study staff. The Biobank interprets the Biobank

refusal to include both withdrawing consent and exercising the right to object. Completing the Biobank refusal form will not retroactively affect results from research already conducted.

The FHRB Biobank website contains more information about the Biobank and our contact persons, and the forms mentioned above (www.fhrb.fi). You can also request that the forms be sent to you by post. Our staff will be happy to provide more information.

Exercising your right to object

Under article 21 of the EU General Data Protection Regulation (GDPR), you (the data subject) have the right to object to the processing of your personal data at any time. After you've objected to the processing of your data, the data controller (the FHRB Biobank) may no longer process it.

As set forth in Section 12a of the Biobank Act, as soon as the Biobank receives notification of a data subject exercising their right to object, it may no longer use or release for biobank research the samples or associated data concerning which the right to object has been exercised.

Contact details:

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