INFORMATION FORM FOR BIOBANK SAMPLE DONORS/Minors

FHRB Biobank (The Finnish Hematology Registry and Clinical Biobank)

Dear patient/parent of a young patient

We ask for your consent to allow your/your child's samples and personal information

- to be collected and stored in the FHRB Biobank
- to be used in biobank research
- to be linked with the information from other registers
- to be handled otherwise

The information is collected and stored in a manner that protects your/your child's privacy.

The release of samples and related data is voluntary. You are free to withdraw or limit your consent at a later date. Whether you decide to allow the use of the samples and related data or not will not affect the care given.

Biobank operations support medical research. The FHRB Biobank is registered in the biobank register maintained by Fimea, and Fimea also monitors the legality of the operations.

A biobank is a unit that collects and maintains samples and related information for the purposes of future research.

Biobank research refers to research that uses samples and/or related data held in the biobank. The purpose of the research is to promote health, to understand disease mechanisms, or to develop products or clinical practices needed in health care and medical care.

Background and objectives of FHRB Biobank

The FHRB Biobank's field of research is the prevention, diagnosis, treatment and follow-up of hematological disorders. Blood disorders are rare as individual diseases, and their treatment can be developed through research. The FHRB Biobank collects, stores and makes available samples and related data for research projects that fall within the FHRB Biobank's field of research. The research studies are often international, and they can be conducted in collaboration with commercial enterprises. The FHRB does not sell samples, but may charge reimbursement of expenses from those doing biobank research.

The research does not directly benefit you/your child, but has a major impact on the treatment of patients with the same disease or blood disorders in general in the near future. The handover of samples to FHRB Biobank will not cause any extra costs to you.

The FHRB Biobank provides information about ongoing research projects on its website at www.hematologinenbiopankki.fi. In addition, you may request in writing from the person in charge of the biobank for information on projects in which your samples have been used.

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Collection, storage and release of samples and related data for research purposes

The collection of samples to the FHRB Biobank requires the consent of the sample donor/guardian. The consent for the FHRB Biopank is requested from patients who have been diagnosed with a disorder of the blood-forming tissue or lymphoid tissue, or who have a hereditary or acquired disease associated with the blood coagulation system or immunological disorder.

Bone marrow and blood samples are collected as follows: in the diagnosis phase, in the remission phase of the disorder (no apparent signs of the disorder) and in case of potential recurrence of the disease. Samples **are taken in connection with other sampling related to treatment** in the hospital responsible for the treatment of the sample donor. The total amount of blood and bone marrow samples collected depends on the weight of the child, the maximum not exceeding 40 ml per sampling. For adolescents, the maximum amounts are 30 ml of bone marrow and 40 ml of blood (venous blood sample) per sampling. Two skin biopsies are also taken from the patient under local aesthesia to determine the congenital genotype.

The FHRB Biobank samples are processed for storage at the Finnish Red Cross Blood Service, and the samples are stored in the Institute for Molecular Medicine Finland (FIMM). The patient data related to the samples is stored in the Biobank's sample and information registry.

The FHRB Biobank collects data from, for example, hospital patient registers. This means collecting all information recorded about the investigation of the disorder at the place of treatment (including results of laboratory tests and imaging, clinical procedures and responses to them, etc.). Additional information to accompany the samples collected by the biobank may be obtained from national social and health care records, such as statutory registers of the National Institute for Health and Welfare (e.g. Care Register for Health Care, Finnish Cancer Registry), Statistics Finland (e.g. causes of death statistics), the Social Insurance Institution of Finland (e.g. register on reimbursements for medicine costs) and the Finnish Institute of Occupational Health (e.g. register of biological exposure measurements) or another biobank if relevant for biobank research. To enable merging of register data, the data recorded includes the personal ID code, which can be viewed by a limited number of biobank staff only. The samples and data are made available for researchers without identification data.

The samples and related information are owned by the FHRB Biobank. The FHRB Biopank Scientific Advisory Board evaluates every application for research material and, based on this evaluation, the biobank management team decides whether any samples and related data are made available for biobank research. In order to be approved, the objectives of the research projects must comply with the principles defined in this information form, and the researchers must be committed to operating in compliance with this information form. You will not be asked for a new consent for every biobank research study being conducted.

Potential further research requests and contacts

The FHRB Biobank may need to contact you later for additional information or samples. The biobank may ask you/your child about your willingness to participate in research conducted by another party not covered by the consent you have given. If you wish, you may use the consent form to refuse any further contacts from the biobank.

You may at any time ask the FHRB Biobank from which sources they have received information about you/your child and for which purposes your/your child's samples and data have been made available. You have the right to receive health-related information as determined based on a sample if it has been obtained by means of certified methods required from health care laboratories and the information is applicable to the prevention and treatment of diseases. A fee is charged for explaining the significance of the information.This fee shall not exceed the expenses incurred in providing the explanation. Any requests concerning provision of information to the biobank shall always be made in writing.

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In connection with biobank research, unexpected clinically significant findings, such as a specific disorder or a genetic defect that exposes the carrier to a disorder, may come up. This information may be surprising and cause confusion or anxiety. For accurate diagnosis of the clinical finding, treatment and the assessment of the prognosis of the disorder, the sample donor is referred to a healthcare service provider and, if necessary, to genetic counselling. If you wish, you may refuse from receiving such information.

Withdrawing consent or limiting it

You have the right to withdraw your consent at any time or to limit it by notifying in writing about your decision to the person responsible of the biobank, who will make the necessary changes in the register. After this, your samples and the relevant data will no longer be made available for new research studies, or they are used or made available in accordance with the limited consent. Due to the technical limitations of the information systems, the FHRB Biobank may not be capable of ensuring under any circumstances that the samples and data would be made available in accordance with the exact limitations only, and, in such situations, it may be necessary to destroy the samples and delete the data completely.

However, any research results obtained from the samples and the relevant data and materials generated from them prior to the reception of the withdrawal of the consent may be used for research in accordance with the applicable legislation.

Risks of biobank operations

Giving of samples to the FHRB Biobank causes minor inconvenience resulting from the time and effort required for the collection of additional samples. Giving a sample to the biobank does not require additional samplings, but there is always a slight risk involved even with routine laboratory tests. From paediatric patients, the skin biopsy sample is taken in connection with other anaesthetic measures and it causes a minor risk of infection. The skin biopsy will leave a small scar in the place where the sample is taken. The hospital's patient injuries insurance guarantees insurance coverage to the patient.

Biobank research may include genetic studies. The investigation of genetic factors may reveal factors influencing future health of the patient and sometimes also information on the characteristics of relatives. Furthermore, it may be possible to link the sample made available for research to you/your child based on the genetic information obtained from the sample, provided that there is a reference sample available. The FHRB Biobank is taking every effort available to minimise the risks associated with the research use of genetic factors by applying high data protection practices and ethical principles.

With the help of the FHRB Biobank, we aim to improve the treatment outcomes of the blood disorder you have/your child has, both in the short and long term.

We are happy to answer any questions you may have related to the FHRB Biobank.

Contact information:

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