DECLARATION FOR SAMPLE DONOR – MINORS

The Finnish Hematology Registry and Clinical Biobank (the FHRB Biobank)

Dear patient/parent of an underage patient,

*We ask you to give your **consent** to the following:*

- *Samples may be collected from you/your child and transferred to and stored by the Biobank.*

*In addition, we ask for your **acceptance** to the following concerning you/your child:*

- *the use of patient records for biobank research*
- *the linking of patient registry data to other registry data*
- *other data processing to the extent required by biobank research.*

The data will be collected and stored in a manner that protects your/your child's privacy.

Sample donation and data disclosure is voluntary. You can later cancel or restrict your consent and acceptance and object to the use of the samples and data. Whether or not samples are donated and data disclosed will not affect any treatment provided. Both your consent and your acceptance are required for the transfer of the samples and attached data to the Biobank.

Biobanking helps support medical research. The FHRB Biobank has been registered in the Biobank Register managed by the Finnish Medicines Agency Fimea, which also monitors the legality of the operations.

*A **biobank** is a unit that collects and stores samples and associated data for use in future research.*

***Biobank research** refers to any research that uses samples and/or associated data stored in a biobank. The purpose of such research is to promote health, to understand disease mechanisms and to develop and improve products and treatment practices within healthcare and medical care.*

The FHRB Biobank: background and purpose

The FHRB Biobank's research area includes the prevention, diagnosis, treatment, and monitoring of hematological diseases. Individual hematological diseases are rare, and research can help improve their treatment. The FHRB Biobank collects, stores and releases samples and associated data for research projects within the Biobank's research area. The research projects, often multinational, may be carried out in collaboration with commercial companies. The FHRB Biobank does not sell samples, but may charge the party/parties carrying out biobank research a fee to cover its costs.

The research will not benefit you/your child directly, but will have a significant impact on the treatment of patients with the same disease or those with hematological diseases in general in the near future. Donating samples to the FHRB Biobank will not result in any additional cost to you. The legal basis for the processing of personal data by the Biobank is public interest in the area of public health (EU General Data Protection Regulation, 2016/679, articles 6(1)e and 9(2)i). 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.

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The FHRB Biobank publishes information about research projects on its website at www.fhrb.fi. You can also request, in writing from the person in charge of the Biobank, a list of the research projects that have used your samples.

Collection and storage of samples and data and their release for research purposes

Collecting samples for the FHRB Biobank requires consent from the donor/donor's guardian. The meaning of the consent will be explained by a professional familiar with biobanking. Consent and acceptance for the FHRB Biobank will be sought from subjects diagnosed with a disease of hematopoietic (blood-forming) tissue or lymphatic tissue, or a hereditary or acquired disease related to a coagulation or immunological disorder.

Bone marrow and blood samples will be collected at diagnosis, remission (no detectable signs of the disease) and any recurrence. Samples will be **collected during treatment-related sampling** at the hospital in charge of the donor's treatment. The total sample volume for both blood and bone marrow will depend on your child's weight, but will not exceed 40 ml per sample collection visit, and in the case of adolescents, 30 ml bone marrow and 40 ml blood (from a vein) per sample collection visit. One skin biopsy sample will also be collected under local anaesthesia for an analysis of the donor's genes at birth.

The FHRB Biobank's samples are processed by the Finnish Red Cross Blood Service and stored by the Institute for Molecular Medicine Finland (FIMM). Patient data associated with the samples is stored in the Biobank's sample and data register.

The FHRB Biobank collects data from sources such as hospital patient registries.

This refers to all data obtained by the treatment unit from examinations related to the disease (including results of laboratory tests and imaging examinations, treatments and responses to treatment etc.). The samples collected by the Biobank can also be linked with data from national healthcare and social welfare registries, including the statutory registers of the Finnish Institute for Health and Welfare (e.g. the Care Register for Health Care and the Finnish Cancer Registry), Statistics Finland (e.g. cause of death statistics), the Social Insurance Institution of Finland, or Kela (e.g. the register concerning special reimbursement for medicinal products), the registries of the Finnish Institute of Occupational Health (e.g. the biological exposure registry) or other biobanks if the data is relevant for biobank research. Such data can be collected and linked to the Biobank's samples and data when Biobank material is released for biobank research. Data stored for purposes of linking registry data includes the donor's personal identity code, which is only accessible to a limited number of Biobank staff members. Biobank samples and data are released to researchers without identifiers.

The samples and associated data are owned by the FHRB Biobank. The FHRB Biobank's Scientific Advisory Board reviews each application for material, and the Biobank's Steering Group makes a decision based on this evaluation as to whether to release samples and data for the biobank research in question. In order to be approved, the purposes of the research project must comply with this Information Sheet and the researchers must commit to acting in compliance with this Information Sheet. You won't be asked for a new consent and acceptance for each biobank study.

Requests for further studies and contacting you

The FHRB Biobank may need to contact you later on for additional information or samples. The Biobank may ask if you/your child would be willing to participate in a study carried out by a third party to which the consent and

acceptance you provided doesn't apply. If you wish, you can choose to refuse further contact using the Consent and Acceptance form.

You can, at any time, ask the FHRB Biobank from what sources data concerning you/your child has been collected and to which parties your/your child's samples and data have been released. You have the right to receive data concerning your/your child's health that was obtained from your/your child's sample if the data was obtained using established methods that healthcare laboratories are required to use and if the data is applicable to disease prevention and treatment. A fee will be charged for an explanation of what the data means. This fee will not exceed the costs incurred in providing the explanation. Any requests for data should always be submitted to the Biobank in writing.

Biobank research may reveal unexpected, clinically significant findings, for example the presence of a disease or a gene defect predisposing you/your child to a disease. This may come as a surprise and may cause confusion or anxiety. For an exact diagnosis, treatment and assessment of prognosis following a clinically significant finding, sample donors will be directed to the relevant healthcare services and if necessary for genetic counselling. If you wish, you may refuse to receive such information.

Consent and acceptance: their voluntary nature, withdrawal and validity

Providing consent and acceptance is voluntary. You/your child will be able to use healthcare services as normal irrespective of whether or not consent and acceptance to biobanking has been provided. You can withdraw your/your child's consent before a sample is collected, or at the latest before the sample and associated data are transferred to the Biobank. You can also object to the use of the samples and data by notifying the Biobank in writing, in which case the Biobank will make the necessary changes to its register. After this, the samples and associated data will no longer be processed or released for use in new studies. Due to the technical constraints of data systems, the FHRB Biobank is not always able to guarantee that samples and data can only be used exactly according to a requested restriction, in which case the samples and data may need to be removed entirely. The right to object to the use of personal data is based on article 21 of the EU General Data Protection Regulation (2016/679). Consent and acceptance for the FHRB Biobank only concern the FHRB Biobank. If consent and acceptance are provided, they are valid until further notice.

The Biobank interprets the Biobank Refusal to include both withdrawing consent and exercising the right to object. However, any research results obtained from and any data sets compiled using the samples and data before the Biobank Refusal form is received may be used in research in accordance with the current legislation.

The risks of biobanking

Donating samples to the FHRB Biobank will cause some minor inconvenience due to the time and trouble involved in collecting further samples. Donating samples to the Biobank will require no additional sample collection visits, but any sample collection, even sample collection for routine laboratory tests, always involves a minor risk. In children, skin biopsies are collected when another procedure is being performed under general anaesthesia. They involve a minor risk of infection and leave a small scar. Patients are covered by the hospital's patient insurance.

Biobank research may include genetic testing. Genetic testing may provide information about factors that will influence the donor's health in the future and sometimes also information about the donor's family members. It may also be possible to link the sample to you/your child based on genetic information obtained from the sample if a reference sample is available. The FHRB Biobank will use all available means to minimize the risks associated with the use of genetic factors in research by adhering to strict data security and ethical principles.

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The purpose of the FHRB Biobank is to help improve the treatment outcomes of your/your child's hematological disease in both the short and long terms.

We will be happy to answer any questions you may have concerning the FHRB Biobank.

Contact details:

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