

The Blood Service Biobank's Declaration for the Sample Donor

You are kindly requested, using the attached Consent and Acceptance form, for your consent to add you to the Blood Service Biobank's register and to collect samples from you. We also request for your consent to collect samples and to hand over the samples and related data to the Blood Service Biobank. In addition, we ask for your consent to inform you about any clinically relevant findings. With the form we request for your acceptance to attach information about you and your state of health to your sample. We also ask for your acceptance to release this data to Biobank research. Both your consent and your acceptance are required for us to be able to transfer the samples and the related data to the Biobank. Information about our work and the meaning of giving your consent and acceptance is presented below.

Summary

- The Blood Service Biobank collects human samples and data for scientific research.
- Participation in biobanking is voluntary. It is based on consent and acceptance, and any decision not to agree will not affect your status as a blood donor.
- A biobank sample is usually taken along with blood group and viral samples when you donate blood. Taking a sample for the Biobank will not affect the total volume of the blood donated.
- Your consent and/or acceptance may also apply to other samples and data previously collected by the Blood Service as part of a blood donation, and to other biobank samples given in the future.
- You have a right to be informed about the studies in which your samples and data have been used. You also have a right to object to the processing of your data.
- Biobank samples and related data are only released for specific approved Biobank research projects that comply with the Blood Service's operating principles and values. The privacy of the sample donor is always protected.

Biobank operations and the Blood Service Biobank

The Biobank is a unit supervised by the authorities and governed by the Biobank Act (688/2012) engaged in the processing of human samples and data. Samples and data are provided for specific approved research projects. Biobank research helps to develop ways to prevent diseases and provides information on the underlying factors, and investigates the effects of the human genome, environment and living habits on the aetiology of diseases. The purpose of biobank research can also be the development of products or treatments for health and medical care. Biobank samples and related data may be used as approved by law in different research studies both within and outside the European Union. Researchers may be charged for the use of the Biobank's services. Research results will be returned to the Biobank to be utilised in other studies.

The Blood Service Biobank's research focuses on health promotion through studies that aim to prevent diseases and identify disease mechanisms. The Blood Service Biobank's research specializes in transfusion medicine. The Finnish Red Cross, Blood Service owns the Blood Service Biobank and the samples under its governance as well as the related data. The Blood Service Biobank is responsible for storing the samples and related data. The purpose of storing

and using the samples and data is scientific research aimed at health promotion.

Biobank samples and data

Biobank samples may be taken as part of donating blood or separately just for the Biobank. Your consent means that your samples and related information collected by the Blood Service during previous blood donations may also be passed on to the Biobank. A biobank sample may be a blood sample, a blood product, or a part of a blood product that cannot be used to treat patients. The sample to be stored may contain blood, blood components (serum, plasma), DNA or cells. Samples and data collected from donors can be stored in the Biobank for up to several decades.

Samples stored by the Biobank are accompanied by information about the sample and the donor that is necessary for research (i.e., the age and sex of the donor, data analyzed from the sample, blood donation history data, the type of sample, and the date and time when the sample was taken) and information about the donor's state of health. The results produced by biobank research, such as information about the individual's genome (genes), are attached to the samples and to the sample donor. The use of genomic information in research is increasing significantly. The Biobank processes specific personal data groups, such as information on

people's health and genome. The Biobank processes this personal data in accordance with Articles 6(1)(e) and 9(2)(i) of the European General Data Protection Regulation (2016/679).

Data from other registers can be combined with samples and data from the Blood Service Biobank, if the information is necessary for carrying out the biobank research. Such registers include those of hospitals (patient documents), other biobanks, national registers of social and healthcare services (e.g., the Finnish Institute for Health and Welfare, THL), Statistics Finland, the Digital and Population Data Services Agency or the Social Insurance Institution (Kela), and other research registers. The data is always combined by the Biobank or other data controller, and the data is always encoded before being handed over to research projects. Information from other registers is not stored in the Blood Service Biobank's register.

You have a right to get information

You have the right to find out which samples and information about you we store, where the information and samples were obtained, and where they have been released to. You can inquire from the Blood Service Biobank what kind of information about your samples has been specified for biobank research, and you have the right to receive an explanation of the meaning of the information. A fee may be charged for explaining the meaning of the information, the fee not exceeding the cost incurred in providing the report. Generally speaking, participation in biobank research does not directly benefit the donor.

Requests for further research and contacting the donor

We ask for your consent to contact you, if the research reveals important information about your health, for example a significant risk of a disease which could be treated or the consequences of which could be prevented. In such case, the Biobank can refer you to appropriate healthcare services. We also ask for your consent to contact you regarding the Biobank's operations (e.g., request to participate in another research or to give a new sample).

The benefits and possible risks of biobank operations to the donor

Giving samples and information for the biobank research does not usually benefit the donor personally. The purpose of the biobank research is to promote public health by investigating the factors behind diseases, or by finding means of

prevention and more effective therapies. Giving a sample has no effect on the total amount of blood donated. Blood products intended for patient use are not dependent on giving a biobank sample. This means that giving a sample to the Biobank has no effect on the safety of blood donation.

Biobank samples and data are only released for specific and ethically evaluated scientific research projects consistent with the Blood Service Biobank's scope of research. The donor's privacy is protected in accordance with the legislation, so that the risk of personal data breach is minimal.

The Biobank processes samples and data in accordance with the requirements of the European General Data Protection Regulation. Data safety is ensured through explicit user agreements and pseudonymization, i.e., by encoding the samples and data so that no individual person can be identified from the material. In countries outside the European Union, adequate levels of data protection are provided through special agreements, as the level of statutory data protection may vary.

Research results and genomic data can also be used in research other than that conducted by the Blood Service Biobank. Data used for this purpose is protected through pseudonymization and released through international databases. Biobank samples and data cannot be used in criminal investigations, administrative decision making regarding the donor, or when assessing employment or insurance agreements. Unauthorised use is a crime.

Giving your consent and acceptance

Giving your consent for collecting samples and giving your acceptance to attach data to the samples is voluntary. Whether or not you give your consent and acceptance will not affect your status as a blood donor in any way. Consent and acceptance must be given as a written document to the Blood Service Biobank and will become valid when the Biobank receives the document. You can give your consent and acceptance by sending a signed form to the Blood Service Biobank or by giving it to the blood donation staff. Your consent and acceptance are valid only for the Blood Service Biobank and are in force for an indefinite period.

Withdrawing your consent and/or exercising your right to object

You can withdraw your consent before giving the sample or at the latest before the sample and the related data are handed over to the Biobank. You can withdraw your consent by providing the Blood

Service Biobank with a signed Biobank Refusal Form. The Biobank will consider the withdrawal to also include the use of the right to object.

The Biobank Refusal Form can also be used to object to the use of your samples and data in the future in accordance with Article 21 of the European General Data Protection Regulation. The above must be done in written Biobank Refusal Form which can be sent direct to the Blood Service Biobank or given to the blood donation staff. Consent withdrawal and/or objection to the use of your personal data become valid once the Blood Service Biobank has received the form. Withdrawing consent and/or exercising the right to object apply only to the Blood Service Biobank. Use of your right to object applies to all your samples and data stored in the Biobank.

After receiving notice that you wish to exercise your right to object (Biobank Refusal Form), the Biobank will no longer be permitted to use or pass on your samples and related data to new research

projects. Your samples will be destroyed, and data will be deleted from the Blood Service Biobank's register (excluding information about your use of the right to object). Once you have exercised your right to object, you will no longer be able to request information from the Biobank, for example about the studies in which your samples and data have been used. Neither will it be possible to obtain any of your personal health data from the Biobank thereafter. The Biobank is no longer permitted to process your personal information once you have exercised your right to object.

Withdrawing consent and/or exercising the right to object does not affect your status as a blood donor in any way. More information about the Blood Service Biobank's operations, contact details and the forms mentioned above can be found on the Blood Service's website (www.veripalvelu.fi). The forms can also be posted to you if you prefer. If you need more information, please don't hesitate to ask the Biobank's staff.

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