

## Blood Service Biobank's declaration for the sample donor prior to giving consent

We request your consent to the collection of samples as well as personal and health-related information in the Blood Service Biobank for use in biobank research. This declaration contains information about the Blood Service Biobank and what giving your consent involves in practical terms.

### Summary

- Biobank is a collection of human biological samples and data, collected for the purposes of medical research and product development.
- Participation in biobank activities is voluntary and consent-based. The decision to not give consent or the subsequent withdrawal of consent will not affect blood donation in any way.
- As a rule, the biobank sample is taken along with blood donation, simultaneously with the collection of blood group and virus test samples. Therefore, the biobank sample does not require extra sampling and will not affect the total amount of donated blood.
- Consent may also relate to similar samples and data collected along with previous blood donations, as well as future follow-up samples.
- You have the right to know which studies your samples and data have been assigned to.
- The Biobank secures sample donors' privacy at all times when assigning samples and the related data for the purposes of biobank research.
- Donors' samples and data may be stored in the Biobank for decades.

### Biobank and the significance of biobank research

A biobank is a unit compliant with the Biobank Act (688/2012), controlled by the authorities, which processes human biological samples and information and transfers them for the purposes of medical research and product development projects. For instance, causes of diseases and their prevention methods, as well as the impacts of genetic, environmental and lifestyle factors on diseases can be clarified with the aid of biobank research. The samples and the related data can be used in various research projects, and in commercial cooperation and product development projects even outside the European Union, as permitted by law. Researchers may be charged a fee for Biobank services. Research results will be returned to the Biobank for use in future studies.

### Blood Service Biobank

The research area of the Blood Service Biobank is health promotion through studies that prevent diseases and identify disease mechanisms. In addition, the Blood Service Biobank is specialised in the specific issues of transfusion medicine from the viewpoints of both the donor and the patient.

### Biobank samples and information

The Finnish Red Cross Blood Service owns the Blood Service Biobank, which is responsible for the storage of biobank samples and information.

Biobank samples can be taken along with blood donation, while participating in scientific research, or specifically for the purposes of the biobank. Blood group or virus test samples taken earlier along with blood donation can also be transferred to the Biobank. The sample stored in the biobank is blood or parts thereof (serum, plasma), DNA or cells. Samples are accompanied by information on the sample and the donor, such as gender, health survey data, sample type, date of sample, research data (biobank research results), and information about the individual's genotype (genes).

Additional information to accompany the sample and donor may be requested from other registers such as, for example, patient records, another biobank, national social and health care records (the National Institute for Health and Welfare Care Register for Health Care, the Cancer Register, etc.), Statistics Finland, the Population Register Centre or registers of the Social Insurance Institution of Finland (e.g. Register on reimbursements for medicine costs), and material compiled by a research project, if the information is necessary for the purposes of carrying out biobank research. The data obtained from the other data controllers is used solely in the research project needing it and it is not stored in the biobank.

The samples may be used for the purpose of investigating the individual genome and its

impacts on health. The use of genetic information in research and daily diagnostics is increasing considerably. Today, it is also possible to map an individual's entire genome, i.e. the hereditary material.

### **You have the right to access information**

Feel free to ask the Blood Service Biobank whether we have samples taken from you and information about you in storage, about the grounds for storage (consent or notification procedure for old samples), from where we obtained your information and where your samples and information have been transferred. You may also ask which information concerning your state of health has been determined in biobank research. However, the results of biobank research are rarely directly exploitable for the benefit of individual donors. If you wish, you also have the possibility to obtain clarification of the significance of the results, but a fee corresponding to the expenses incurred by verifying and clarifying the information may be charged.

### **Possible further research requests and contacts**

The consent form contains a separate question about whether we may contact you if the research has identified significant information about your state of health, such as a serious risk of illness for which there is effective treatment or the effects of which can be prevented. The biobank cannot provide treatment for the sample donor but will guide the donor to healthcare services as needed. We also ask for a separate consent to be able to enquire about your willingness to participate in research or sampling that this consent does not allow. Such situations may include, for example, a request to participate in a clinical drug trial or to donate a new sample.

### **The benefits and potential disadvantages of biobank activities to the sample donor**

In most cases, individual health benefits cannot be expected from the donation of samples and provision of information to biobank research. The aim is to devise, at a general level, more effective treatments and methods of preventing illness for the benefit of the entire population. The appropriate prerequisites for research are assessed in advance, so the risk of misuse of Biobank's samples and data is very low. The Biobank processes samples and information in

accordance with data security requirements for confidential information. Data security is ensured by coding the samples and making precise material and data transfer agreements. 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 genome data can be shared with other researchers through international databases. This is done without identification data of individuals, thus protecting data privacy.

Biobank's samples and information may not be used for the purposes of criminal investigation, administrative decision-making on the sample donor, or in the evaluation of an employment relationship or insurance contract. Unauthorised use is a criminal offence.

### **Voluntary consent, its withdrawal and period of validity**

The consent is voluntary and valid until further notice. Acting as a blood donor is completely independent of biobank consent. You can withdraw your consent at any time.

The consent, its withdrawal, modification, or prohibition will take effect as soon as the Biobank receives the related information. Withdrawal of consent or a prohibition do not retrospectively affect material transferred from the Biobank for biobank research prior to the prohibition or withdrawal. Withdrawal of consent does not always mean that a sample is destroyed from the biobank or personal data deleted. For example, in order to verify the accuracy of research results, it may sometimes be necessary to store the samples and other documentation used in the study.

You may grant consent, withdraw or amend it by submitting the signed form directly to the Blood Service Biobank or by handing it over to Blood Service personnel.

The Blood Service website ([www.bloodservice.fi](http://www.bloodservice.fi)) provides further information on the activities and contact persons of the Blood Service Biobank, as well as the abovementioned forms. The forms can also be mailed to you if you wish. The Biobank personnel will be happy to provide additional information.