

Statement by Biobank Borealis of Northern Finland for the purpose of giving consent and approval

We ask for your consent to collect your samples and related data in the biobank. This applies to samples already collected from you earlier, samples collected in other contexts (e.g. examinations and diagnostics), as well as samples collected in the future. In this form, you may also give your consent to be informed of clinically significant findings. **We also ask for your approval** to attach to your samples information on the factors affecting your state of health and health, in which case they may also be handed over from the biobank for research purposes in the future. The transfer of samples and related data to the biobank requires both consent and approval.

A biobank is a government-controlled unit under the Biobank Act (688/2012) where samples and related specific personal data (in particular health and genetic data) are processed for the purposes of health science research. A biobank provides samples and information for national and international research projects. A biobank's collections may also include materials intended for more restricted use. Once the research has been concluded, the results obtained from the samples are returned to the biobank to be used in new research.

Biobank samples and data. Samples can be collected in connection with participation in sampling for treatment or for scientific research, or occasionally, specifically for the biobank. Previously collected samples may also be transferred to the biobank. Biobank Borealis operates in the wellbeing services counties of North Ostrobothnia, Lapland, Kainuu, and Central Ostrobothnia, who also own the samples, unless otherwise agreed when the samples are transferred. Samples include, for example, tissue (biopsies, fine-needle or bone marrow samples, samples from exfoliated cells, tissue extracted in surgery, cerebrospinal fluid), blood, secretions (urine, saliva, sputum, stool), or DNA or cells isolated from samples. Information about the sample and the sample donor, such as age, gender, and health information (e.g. diagnoses, medical procedures, treatments, laboratory results, imaging records) and data determined from the sample, e.g. genotype, will be attached to the samples. Data may be requested, for instance, from the sample donor, patient records, national social and healthcare registers (such as hospital discharge, tumor, and Kela's special reimbursement registers), medicine registers and Statistics Finland registers, Digital and Population Data Services Agency, or data collected by research projects. Information disclosed to a biobank researcher may be accompanied by information from the above registers supporting biobank research. The data is specific to the research project, and for the purpose of the research, researchers have applied for a separate permit from the controller or other competent entity (Findata). For the purposes of merging register information, the biobank may assign the personal identity code of the sample donor to the controller, who shall add the information contained in the person's register to the information obtained from the biobank.

Giving consent and approval. Consent to sampling and approval to the attachment of data is optional. You may give your consent and approval by submitting a signed consent and approval form to Biobank Borealis or to

treatment or research personnel. The form can be found on our website (see below) or it can be mailed to you. An adult may also fill out the form at www.omaoys.fi. Healthcare services are available to you as usual even if you do not give your consent and approval. The given consent is valid indefinitely. Biobank Borealis' consent and approval only apply to Biobank Borealis.

Withdrawal of consent and/or exercise of the right to object. Consent is a prerequisite for taking a sample. You may withdraw your consent before the sample is given or, at the latest, before the sample and related information is handed over to the biobank. After withdrawal, no samples will be collected in the biobank. After a sample has been collected and handed over to the biobank, you may manage the use of your own data or prevent the use of your data in the biobank by using your right to object (Article 21 of the EU General Data Protection Regulation). You may object to the processing of some or all of your personal data. In practice, also partial objection to the processing of personal data results in the prevention of the use of all personal data. Please note that the biobank interprets the withdrawal of consent as also including the exercise of the right to object. Once the notification of the exercising of the right to object has reached the biobank, your samples and data will no longer be used or provided for new research. Your samples will be destroyed and your data will, as a rule, be removed from the biobank register (except for the information on the refusal itself). Any data on your state of health potentially analysed from your biobank sample will also be deleted.

You may withdraw your consent or exercise your right to object by submitting a signed refusal form to Biobank Borealis or to treatment or research personnel. The form can be found on our website (see below) or it can be mailed to you. An adult may also file a refusal at www.omaoys.fi. The withdrawal of consent and/or the exercise of the right to object shall take effect after the biobank has received the information on them, and the declarations only concern Biobank Boreal.

Advantages and disadvantages to the sample donor. There is generally no immediate therapeutic advantage to be expected from providing samples and data to the biobank, since the biobank exists primarily for research purposes. The biobank cannot guarantee the quality of the data analysed from the samples, nor that the research will reveal information that is significant to you, or that the data would be available to you or your healthcare. The biobank handles samples and data in accordance with the data protection requirements for confidential information. The name of the sample donor and other identification data are replaced by a code, whose decryption key is stored separately. Identification of an individual person from the coded information is almost impossible. Identifiable samples or data can only be released where there is a justified need, such as the need to link the samples or data from the biobank to other data, for example, data already collected by the researcher. Samples and data may also be transferred for research purposes to countries outside the EU and EEA, where there is variation in the statutory level of data protection. Data protection is safeguarded by coding the samples and data, and by making precise agreements for their processing.

Consent and approval document

The processing of personal data is based on the Biobank Act (688/2012, section 5) and the EU General Data Protection Regulation (Article 6(1)(e), Article 9(2)(i)). Samples and data from the Biobank may not be used in criminal investigations, in administrative or other decision-making concerning the sample donor, in assessing or determining fitness for work, or in decision-making by credit or insurance institutions.

TO THE BIOBANK ARCHIVES

Consent and approval to Biobank Borealis

With my signature I confirm that I have read and understood the statement and accordingly give my consent to Biobank Borealis. With my consent, my sample may be collected and handed over to Biobank Borealis. In addition, I accept that information about my state of health and information affecting my health received from me may be attached to the samples collected or transferred to the biobank. Biobank Borealis may hand over my samples and data for biobank research. I can withdraw my consent or object to the processing of my personal data at the biobank by signing a refusal form.

In addition, I consent to the biobank contacting me in the following cases:

To report a significant health finding revealed by a sample.

Yes No

To inquire about my willingness to give additional samples or participate in research not covered by this consent.

Yes No

Personal identity code

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Full name of the person giving the consent and approval

Address _____

Signature and date _____

You can return the document when you arrive at the hospital.

Return (postage paid): **POHDE interdepartmental mail address:**
 Biobank Borealis of Northern Finland (for Pohde staff only)
 Oulu University Hospital "Biopankki Borealis"
 TUNNUS: 5001312
 00003 VASTAUSLÄHETYS

Biobank or other healthcare personnel to fill in
 Recipient (date, name, and signature): _____

At your request, you have the right, at any time, to obtain information on the research use of your samples and information. Forms, requests for information, and contacts: see the contact information below. Electronic services www.omaoy.fi.

Biobank Borealis is owned by the wellbeing services counties of North Ostrobothnia, Lapland, Kainuu, and Central Ostrobothnia, the University of Oulu, and the Nordlab wellbeing enterprise. Its research focuses on the promotion of the health of the population, identification of the factors impacting disease mechanisms, prevention of diseases, and the development of products and treatment practices that promote the population's wellbeing and health or are used in medical care.



TO THE PERSON GIVING THE CONSENT AND APPROVAL

Consent and approval to Biobank Borealis

With my signature I confirm that I have read and understood the statement and accordingly give my consent to Biobank Borealis. With my consent, my sample may be collected and handed over to Biobank Borealis. In addition, I accept that information about my state of health and information affecting my health received from me may be attached to the samples collected or transferred to the biobank. Biobank Borealis may hand over my samples and data for biobank research. I can withdraw my consent or object to the processing of my personal data at the biobank by signing a refusal form.

In addition, I consent to the biobank contacting me in the following cases:

To report a significant health finding revealed by a sample.

Yes No

To inquire about my willingness to give additional samples or participate in research not covered by this consent.

Yes No

Personal identity code

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Full name of the person giving the consent and approval

Address _____

Signature and date _____

You can return the document when you arrive at the hospital.

Return (postage paid): **POHDE interdepartmental mail address:**
 Biobank Borealis of Northern Finland (for Pohde staff only)
 Oulu University Hospital "Biopankki Borealis"
 TUNNUS: 5001312
 00003 VASTAUSLÄHETYS

Biobank or other healthcare personnel to fill in

Recipient (date, name, and signature): _____

At your request, you have the right, at any time, to obtain information on the research use of your samples and information. Forms, requests for information, and contacts: see the contact information below. Electronic services www.omaoy.fi.

Biobank Borealis is owned by the wellbeing services counties of North Ostrobothnia, Lapland, Kainuu, and Central Ostrobothnia, the University of Oulu, and the Nordlab wellbeing enterprise. Its research focuses on the promotion of the health of the population, identification of the factors impacting disease mechanisms, prevention of diseases, and the development of products and treatment practices that promote the population's wellbeing and health or are used in medical care.

