

Name and CPR no (label)

Consent to the disclosure of health information for research and the retention of biological material from patients at Copenhagen University Hospital.

In connection with your treatment at Copenhagen University Hospital we would like to store samples from you in a biobank. The samples may be used in the future for laboratory tests within your disease category, to reveal relationships between heredity, environment, lifestyle, infections, other diseases and the disease that you have. The aim is to improve the diagnosis and treatment of patients with your disease.

All research projects that make use of the biobank have to be approved by the Committee on Health Research Ethics and registered with the Danish Data Protection Agency.

Information about your disease, as described above, will be included in a way that does not disclose your identity (anonymized).

Blood and other biological material may be stored for later scientific use within my disease category/diagnosis.

Yes
☐No
☐

If I change my mind, I am aware that I can contact the staff at Copenhagen University Hospital to obtain the booklet "Your tissue, your choice", published by the Ministry of Health, which will tell me how to withdraw my consent *without this affecting my treatment now or in the future*.

Date: _____ Signature: _____

Consent obtained from: _____

Please hand the completed declaration to the staff at Copenhagen University Hospital when you are admitted.

Research to benefit future patients

We would like to ask your permission for us to store biological material from you in the PERSIMUNE biobank for the purposes of future research into immune defences against infections.

The PERSIMUNE biobank is used to store various biological material from patients who could be at risk of infection because their immune systems may not be working properly. The material from the biobank will later be used in research projects aimed at gaining a better understanding of the medical factors behind the risk of developing an infection.

The precise focus of these research projects has not yet been defined. The biological material will generally undergo laboratory analyses to examine how the immune system works, as well as the metabolism and any ongoing infection. These analyses may reveal trace elements. There may also be analyses of the genetic information contained in the biological material, in order to understand the relevance of heredity to the functioning of a person's immune system and the risk of picking up an infection. The analyses will focus both on the patient's own samples and on the micro-organisms that may be present in the material.

Data from these new analyses will be linked to information in your patient record to enable the best possible interpretation of the results. The biological material you donate to the PERSIMUNE biobank are therefore very important to the work of the researchers to develop new diagnoses and treatments to benefit future patients. Laboratory analyses and data processing of the results will be performed at Copenhagen University Hospital or by our project partners in public institutions in EU countries.

The blood samples for the PERSIMUNE biobank will be taken at the same time as other blood samples obtained as part of your treatment, so will not involve any extra needle pricks. Blood will be taken in three sampling tubes (2 x 9 ml and 1 x 3 ml), and this modest quantity has no effect on health.

The blood sample – and possible saliva and stool samples – will be taken when you give your consent, after 3-6 months and then once a year for as long as you are being monitored at Copenhagen University Hospital. The sampling schedule may be changed if you receive treatment that affects your immune system or you show symptoms of acute diminished resistance to infections.

We will record and store the samples with the approval of the Danish Data Protection Agency. We treat personal information with complete confidentiality. Before we use samples from the biobank for research projects, each project has to be approved by the Committee on Health Research Ethics and the Data Protection Agency.

Your participation is voluntary, and your decision will not affect your treatment now or in the future in any way. If you choose to take part and later change your mind, you can withdraw your consent at any time with immediate effect, without having to give any reasons.

If you later change your mind, please ensure that your decision is recorded in the Use of Tissue Register. You can do this by completing the form "Your tissue, your choice", and sending it to the Use of Tissue Register at the Danish Health and Medicines Authority. If you need help with this, you can contact the staff at the clinic or the PERSIMUNE centre.

Thank you for taking the time to read this information and thinking about the biobank.

Please let us know whether you agree to us storing samples in the PERSIMUNE biobank by completing and signing the attached consent to the disclosure of health information and the retention of biological material.

Best regards,

The staff at PERSIMUNE