Name and personal ID No. (label)

Consent to storage of biological material from patients at Rigshospitalet.

As a parent of

Name: _____ Personal ID No.:_____

I accept that, as part of my child's treatment at Rigshospitalet, samples are stored in a biobank. In the future, the samples may be used for laboratory studies to shed light on links between heredity, environment, lifestyle, infections and other diseases - and thus the illness my child has - and will be used with information from my child's disease/diagnosis record.

The purpose is to improve the diagnosis and treatment of patients with the same disease. All research projects that emanate from the biobank must be approved by the Scientific Ethics Committee and notified to the Data Inspectorate, and the information about your child's illness, as described in the section above, will be included in a way that does not reveal the child's identity (in anonymous form).

Blood, other biological material and medical record data may be stored for later scientific use within my child's disease category/diagnosis.

Yes ☐ No ☐

If I change my mind I am aware that I can contact the staff at Rigshospitalet and obtain the pamphlet “Your tissue, your choice” published by the Ministry of the Interior and Health, which offers guidance on withdrawing consent *without this affecting current or future treatment.*

Date: _____ Signature: _____

Date: _____ Signature: _____

Consent obtained by:

Please hand the completed form to the staff

Information for parents: Research for the benefit of future patients

We wish to ask if you are willing to let your child participate in a PERSIMUNE biobank for future research into the immune defences against infection.

We at Rigshospitalet have established a biobank where biological material from patients is stored. The material consists of blood and possibly saliva and stool samples which will later be used for research projects aimed at shedding light on diseases in patients who are at increased risk of developing infections or have already developed a serious infection.

The biological material will be examined by laboratory analyses focusing on the child itself (genes, proteins and metabolic products) and on the micro-organisms (bacteria and viruses) found in the material. This will provide new knowledge about the immune system and the type of infections. Data from these new analyses will be linked to the information in your child's medical record to allow optimum interpretation of the results.

The biological material your child donates to the PERSIMUNE biobank is therefore important for the work on developing new diagnostics and treatment for the benefit of future patients. But participation in the biobank will not have a direct impact on the treatment of your child.

The blood samples for PERSIMUNE biobank are taken at the same time as other blood samples collected as part of the treatment and will therefore not involve additional needles. The amount of blood taken is adjusted to the age of the child and is of no significance to health:

- **Neonatal**: Blood is collected in a collection tube (1 x 350 µl and blood drops on paper)
- **1-12 months**: Blood is collected in two collection tubes (2 x 2 ml)
- **1-5 years**: Blood is collected in two collection tubes (1 x 9 ml and 1 x 3 ml)
- **Over 5 years**: Blood is collected in three collection tubes (2 x 9 ml and 1 x 3 ml)

The blood sample - and possibly saliva and stool samples - is taken, subject to consent being given, after 3-6 months and then annually, as long as your child's treatment at Rigshospitalet continues.

Laboratory analyses and data processing of results will be carried out at Rigshospitalet or by our partners at public institutions in EU countries.

We register and store the samples according to the Data Inspectorate's approval, and we handle personal information entirely confidentially. Before using samples from the biobank for research projects, each research project must be approved by the Scientific Ethics Committee and the Data Inspectorate.

Allowing your child to participate is voluntary, and your decision will not affect current or future treatment in any way. If you choose to let your child participate and later change your mind, please make sure your decision is registered in the Registry for Use of Tissue. You can do this by completing the form “Your tissue, your choice”, which you must send to the National Board of Health's Registry for Use of Tissue. If you need help with this, contact the clinic staff or the PERSIMUNE Centre.

Thank you for taking the time to read this information and considering the issue of the biobank.

We would ask you to decide whether to allow us to store samples from your child in PERSIMUNE biobank by completing and signing the accompanying ***Consent to storage of biological material from patients at Rigshospitalet.***

Yours faithfully,

The PERSIMUNE staff

Information on PERSIMUNE can be obtained from CHIP, Clinic for Infectious Diseases, Section 2100, Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen Ø. Tel.: 35455757 (between 9 a.m. - 3 p.m). E-mail: persimune.rigshospitalet@regionh.dk