

Registry for Pancreatic Patients

**PATIENT INFORMATION**

**- BLOOD SAMPLING -**

Pathophysiologic and genetic investigations of pancreatic diseases

**(individual with legal capacity above the age of 18 yrs)**

Dear Patient,

Because of your abdominal complaints, your gastroenterologist/surgeon ordered a blood test.

Your doctor and the institution responsible for your treatment take part in an international research cooperation together with the First Department of Medicine, University of Szeged, Hungary.

**Please read the below information** thoroughly, and **please contribute** to our research efforts to help patients with your blood sample. Your participation is voluntary. You may refuse or withdraw your consent to provide your blood sample. Refusing or withdrawing your consent will not result in any penalty or loss of benefits, your treatment will not be altered.

**The aim of this study** is to understand the development and the possible genetic background of your disease. Our study may lead to information that substantially helps to better diagnose and treat the disease you are suffering from. Our results may shorten the time of treatment or may improve the overall outcome of the disease in the future. The aim of the study is to reveal the genetic background behind the development of pancreatic diseases.

**Advantages and disadvantages of participation:** the participation in this research project will not have any influence on your health condition, you will not have any advantage or disadvantage originating from the participation. Participation will not imply any additional intervention or pain.

**Your consent is voluntary, you may withdraw your consent without reasoning at any time either verbally or in writing. The withdrawal will not result in any penalty or loss of benefits.**

**Research protocol and data management:**

According to the recommendation of the Ministry of Health Article 4, paragraph 3 of decree No. 23/2002, we planned the sampling **without any additional medical intervention**.

Type of sampling: **Blood sampling**

During blood sampling (ordered by your doctor independently from our research) two more small tubes of blood (less than 10ml) would be taken. This won't mean extra puncture or pain. It is not harmful to your health in any way. During a voluntary blood donation, donors give 40 times more amount of blood without any problem.

The sample receives a code number, your name is known only to your treating doctor and the researcher doctor.

Blood samples are analysed. The results of the analysis will not alter your treatment but may help to treat diseases in the future.

We make genetic analysis' on blood samples. Data and codes are stored separately. Registration of coded genetic samples and personal data are not connected.

**Duration of the research, possibility to withdraw the consent to participate:**

According to the 23§ and 26§ of the XXI. Act, 2008, we keep a registry of all data and samples stored in the Biobank for at least 30 years from the data collection, except the individual withdraws the consent of participation in the genetic study. In case of withdrawal, after informing the individual, all genetic data and samples will be destroyed.

**Possible risks:** during the study the patient will not get any treatment and there is no intervention which is unknown in gastroenterology or surgery, **there is no specific risk of sampling.** The intervention is independent from the research, it would be done anyway because of therapeutic reasons. These examinations are useful as help to reveal the pathophysiologic and genetic background of pancreatic diseases, thus they may lead to diagnostic and therapeutic solutions in the future. The treating personnel complies with safety regulations.

In case you have questions concerning the study, please turn to your treating doctor. Later, if you are interested in the development of the research project, please ask Dr. Péter Hegyi (tel.: +36 62 545 200, e-mail: hegyi.peter@med.u-szeged.hu).

**Yours sincerely:**

.....  
Date

.....  
Doctor informing the patient

.....  
Institution

|                                      |
|--------------------------------------|
| <b>NAME:</b><br><b>Insurance no:</b> |
|--------------------------------------|

|                           |
|---------------------------|
| <b>Blood sample code:</b> |
|---------------------------|

|                           |
|---------------------------|
| <b>Place of sampling:</b> |
|---------------------------|

**Informed Consent Form**

Pathophysiologic and genetic investigations of pancreatic diseases  
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**After reading the patient information and listening the doctor providing information I have understood the aim of this study. I give my consent to blood sampling and to use my data for scientific purposes and to release them in publications without mentioning my name.**

Furthermore I give my consent to store my data and blood sample at the place of the study, during the time of the study or at least 30 years from data and sample collection.

.....  
Date

.....  
signature of the participant (patient)

.....  
Date

.....  
signature of the researcher/doctor

.....  
Date

.....  
signature of the coordinator of the research