



PROTOCOL

1. Introduction

The ECEPSG Biobank and Registry for Pancreatic Patients (ECEPSG RPP) was initiated by the Hungarian Pancreatic Study Group and is dedicated to understand the development and current practice of treatment of pancreatic diseases and serve as a database for genetic studies. These diseases include acute, chronic autoimmune pancreatitis and pancreatic cancer. Centers from Eastern and Central Europe are expected to join, but centers from other regions are also welcome.

2. Ethical issues

The Registry for Pancreatic Patients – that was established for recording data of patients with pancreatic diseases – had received the ethical and biobank permission in 2012. (TUKEB-22254-1/2012/EKU and IF 702-19/2012).

Blood sampling is done when a gastroenterologist or surgeon order laboratory examination, no further intervention is needed. Patients are allowed to be enrolled only upon their written informed consent.

3. Objectives

The objectives are:

- to document the clinical course of pancreatic diseases including acute and chronic pancreatitis, autoimmune pancreatitis, pancreatic cancer
- to develop a database for genetic studies
- to establish a network for possible research cooperations in Central and Eastern Europe

4. Enrollment Procedures

Enrollment of patients will occur in an official healthcare center by a clinician.

Joining of healthcare centers:

- The study is open for all centres which can provide valuable and precise data.
- A Letter of Intent to Join (Appendix 1.) should be signed and send via e-mail to the following address: hpsg.info@gmail.com
- Registration on the [www.pancreas.hu](http://opr2.pancreas.hu) website: <http://opr2.pancreas.hu/en/user/register>

Patient enrollment:

- The patient should be informed on the purpose of the research and blood sampling and the Patient Informed Consent Form should be signed (Appendix 2.)
- Blood samples should be taken according to point 5.1.

5. What is collected?

5.1. Blood Samples:

We collect whole blood from patients with pancreatic diseases (acute pancreatitis, chronic pancreatitis, autoimmune pancreatitis, pancreatic cancer). 2 EDTA tubes should be collected, stored at -20 °C and delivered to the Biobank at the University of Szeged.

Control blood samples are also collected and stored from volunteer participants not suffering from any pancreatic diseases (healthy for blood donation).

5.2. Clinical data:

Accompanying clinical information is adjusted to the different diagnoses and include the following information:

- Details from the patient's medical history - pancreatic diseases, smoking and drinking habits, pancreatic diseases in the family, other diseases, etc.
- Etiology
- Complaints, symptoms - abdominal complains, nausea, vomiting, fever, appetite, weight loss
- State of the patient - blood pressure, heart rate, respiratory rate, body temperature, jaundice
- Laboratory parameters
- Imaging examination descriptions
- Other examinations - histology, functional examinations
- Interventions – endoscopic, surgical
- Therapies – conservative, oncological
- Complications

6. Sample and data access policy

6.1. Who can access samples and clinical data?

Researchers actively contributing to the Biobank and Registry or collaborating researchers. The use of samples and data are free of charge and should serve for research purposes only. An application should be made for accessing samples and data.

6.2. Applications for use of samples and data

- An expression of interest should be made first by e-mail to the research coordinator shortly describing the type of samples and data in order to find out whether the samples, data required are available and the same set of samples and data has not been used yet for the same research purposes.

Research coordinator:

Péter Hegyi

HPSG Chair

e-mail: p.hegyi@tm-pte.org, hpsg.info@gmail.com

- If the presented research is feasible a formal application should be made describing the full scientific proposal, using the HPSG Biobank and Registry Project Application Form. Once the form has been completed, a signed copy should be e-mailed and posted to the following address:

EASTERN AND CENTRAL EUROPEAN PANCREATIC STUDY GROUPS

Biobank and Registry for Pancreatic Patients



Prof. Dr. Péter Hegyi
Hungarian Pancreatic Study Group
First Department of Medicine
University of Szeged
8-10 Korányi fasor, 6720 Szeged, Hungary

- A Review Board (specialist for the disease group, clinician, research coordinator) will evaluate the proposal and the applicant will be informed of the decision together with the information on the delivery time and form of the samples and data.

6.3..Publications

Any results based on the data of the HPSG Registry for Pancreatic Patients, can only be published with the consent of the HPSG.

7. Technical support

All forms and documents are available on the www.pancreas.hu website.
Please turn to the team in Szeged should you have any questions or problems.

Contact:

Andrea Szentesi

e-mail: szentesai@gmail.com or hpsg.info@gmail.com

Tel.: +36 70 293 7537



APPENDIX 1.

CSATLAKOZÁSI NYILATKOZAT

Alulírott..... adatgyűjtőként/kutatóként csatlakozni kívánok a Dr. Hegyi Péter által vezetett "Pankreász megbetegedések pathofiziológiai és genetikai in vitro vizsgálata" című kutatási projektbe. A kutatás során vállalom az Eü. M. 23/2002. számú rendelet betartását.

Adat és mintagyűjtési helyként munkahelyemet, a következő intézetet jelölöm meg:

Intézet:

Osztály:

Város:

e-mail:

Tel:

.....
date

.....
signature

LETTER OF INTENT TO JOIN THE RESEARCH PROJECT

I hereby express my intent to join the research project "Pathophysiologic and genetic investigations of pancreatic diseases" led by principal investigator Dr. Peter Hegyi. In my research I will abide by the regulations #23/2002 set forth by the Hungarian Ministry of Health.

Work will take place in my laboratory at the

Department:

Institute:

City:

Country:

E-mail:

Tel:

.....
full name

.....
date

.....
signature

**Az űrlapot kérjük pdf formátumban aláírva küldje el a hpsg.info@gmail.com e-mail címre.
Please send the signed form (as a pdf file) to hpsg.info@gmail.com.**



APPENDIX 2.

**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.

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PANCREATIC STUDY GROUPS
Biobank and Registry for Pancreatic Patients**



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 personal 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

.....
Name of the doctor informing the patient

.....
signature

.....
institution



NAME:
ID no:

Blood sample code:

Place of sampling:

Informed Consent Form

Pathophysiologic and genetic investigations of pancreatic diseases

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

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.

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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



APPENDIX 3.

RESEARCH PROJECT APPLICATION FORM

Principal Investigator:

Title:

First name:

Surname:

Institution:

Address:

Postcode:

Phone number:

e-mail address:

Co-Investigator:

Title:

First name:

Surname:

Institution:

e-mail address:

Co-Investigator:

Title:

First name:

Surname:

Institution:

e-mail address:

Project Details:

Title of the Study:

Background:

(Please cover the following: literature review, hypothesis, relevance, how results will be used?)

Study details:

(proposed length of study, methods, data storage)

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Place of the Study:
(Institution, departments, laboratory)

Storage of samples:
(location, tracking of samples)

Type of samples required:

Number of samples required:

Accompanying clinical data required:

Shipping address:

.....
Date:

.....
signature

Please return the completed form electronically to
Prof. Dr. Péter Hegyi
p.hegyi@tm-pte.org or hpsg.info@gmail.com and please post the signed paper copy to the following
address:

Prof. Dr. Péter Hegyi
Hungarian Pancreatic Study Group
First Department of Medicine
University of Szeged
8-10 Korányi fasor, 6720 Szeged, Hungary