

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). We renewed it in 2019. (17787-8/2020/EÜIG)

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 (<https://tm-centre.org/en/registries/ap/>) should be signed and send via e-mail to the following address: registries@tm-centre.org
- Registration on the website: <https://registry.tm-centre.org/registration>

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 (<https://tm-centre.org/en/registries/ap/>)
- 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 x 6ml 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:

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 <https://tm-centre.org/en/registries/acute-pancreatitis-registry/> website.

Please ask us if you have any questions or problems:

Contact:

Vivien Vass

patient registry coordinator

e-mail: registries@tm-centre.org

phone: +36 72 536 000 *31885