PATIENT INFORMATION LEAFLET

DATA PROTECTION

(for patients over 18 years of age)

Dear Sir/Madam,

Our Dear Patient,

Please read this information sheet in which we briefly summarize our research project related to pancreatic diseases titled **"REAPPEAR"**, and for which we ask for your consent to participate.

Identification Data of the Study

Title of Research: **"Re**current **A**ccute **P**ancreatitis **P**revention by the **E**limination of **A**lcohol and Ciga**r**ette Smoking **(REAPPEAR)"**

Chief Investigator: **Prof. Dr. Péter Hegyi** Supervisor, University of Pécs, Medical School, Institute for Translational Medicine, 12 Szigeti Street, Pécs, H-7624.

Anticipated Duration of Research: **5 years from the issuance of the approval (04.10.2025)**

Number of Participants to Be Included: **approx. 364 people.**

The approval required to start the research has been obtained from the Hungarian **National Center for Public Health and Health Sciences (NNGYK)** issued with the following registration number: **40394-10/2020/EÜIG.**

The Purpose and Course of the Study

After pancreatitis, 20% of patients may have recurrent episodes. The purpose of this study is to determine whether participation in an alcohol and smoking cessation program effectively reduces the number of recurrent episodes, and to what extent alcohol and smoking play a role in the development of new episodes. To this end, you and other study participants will be randomly assigned to one of two study groups. Before leaving the hospital, you have taken part/will take part in a discussion to help you stop drinking alcohol and smoking. If you enter the withdrawal program, we will repeat this conversation every three months for two years. If you are placed in the other study group, we will interview you and examine you after one or two years, but we will not repeat the conversation. At each visit, we will ask you to fill out a few short questionnaires about your drinking and smoking habits, your quality of life and your social situation. We will also measure your blood pressure and weight. The visits will take place at the regionally competent center, at the pre-arranged place and time.

Your doctor is participating in a research collaboration, during which we are investigating the effects of a cessation program and the cessation of alcohol and smoking on recurrent episodes of pancreatitis.

From September 1, 2020, we ask for the consent of all patients examined and treated for pancreatitis, in whom the role of alcohol consumption in the development of pancreatitis has been established and who smoke.

Possible and Expected Consequences

Participating in the study helps you quit alcohol and smoking, which has a positive effect on your health and pancreatic disease. The planned research has no effect on the diagnosis, treatment plan, and recovery time of your illness (during your current hospital treatment); however, it may reduce the likelihood of subsequent, repeated episodes of pancreatitis and possible complications, and it may also have health-improving effects in other areas (weight loss, decreased risk of heart and vascular diseases).

You should not expect any risks or inconveniences in connection with data recording, and you do not have to expect the occurrence of unforeseen events as a result of the research.

Risks and Mitigation of Damages

Given that participation does not affect the process of patient care, and that all of the lifestyle changes proposed within the study have a beneficial effect on your health and pancreatic disease, there are no specific risks of participation. The Patient Rights Representative (name: ……, contact: ……..) of your treatment institution can provide assistance with questions that arise during normal patient care.

Reimbursement of Expenses

The patients in the study do not receive benefits for participating in the research.

Data Management and Protection

During the study, we record your medical history, as well as your clinical data during and after the study, which of course will be treated in accordance with medical confidentiality. In the papers prepared from the survey, the data will be presented anonymously and in an aggregated form, so it will not be possible to draw any conclusions from them regarding your person. You will remain anonymous in all respects, and data will be processed in accordance with the Hungarian Act on the management and protection of personal data.

Applicable legal regulations governing data protection: Regulation 2016/679 of the European Parliament and the Council on the protection of natural persons with regard to the processing of personal data and on the free flow of such data, as well as on the repeal of Regulation 95/46/EC, regulates at the European level the management and protection of personal data of individuals. CXII of 2011. Act on the right to informational self-determination and freedom of information, with amendments effective from July 1, 2018. XLVII of 1997. Act on the management and protection of health and related personal data.

The manager of the data collected in the study is the University of Pécs. The university's Data Protection Officer is Dr. László Gergely Szőke, e-mail: adatvedelem@pte.hu, tel.: (72) 501 599 / 23321. The university's Health Data Protection Officer is Dr. Krisztina Farkas, e-mail:egeszsegugyiadatvedelem@pte.hu, tel.: (72) +36 30/8931901.

Under the conditions specified in the data management contract, UP may use additional data processors for the electronic storage of data and data transmission in compliance with the rules of the GDPR. When submitting the permit, the following two data processors participate in the above processes:

1) Translational Medicine Foundation, 52/d Pálfy Strt. Szeged, 6725.

2) Digital Kft., 83 Csongrády Av. Szeged 6723.

In relation to data management, you can file a complaint with the Hungarian Authority for Data Protection and Freedom of Information, or go to court in the event of a violation of your data management rights. In Hungary, the Data Protection Supervisory Authority is the National Data Protection and Freedom of Information Authority (22/C Szilágyi Erzsébet Alley Budapest 1125; phone number: 06-1-391-1400, e-mail: ugyfelszolgalat@naih.hu, website:www.naih.hu).

Consent

Of course, if you do not want to participate in the study, we will respect your decision and assure you that this will not affect your further care or the way you are treated. At any time, you have the opportunity to inquire about the progress and results of the study from the Chief Investigator, whose contact information you will receive.

If you have any questions about the study, please feel free to contact your doctor. In the future, if you would like to know the progress of the examinations and the progress of the research project, please contact Prof. Dr. Péter Hegyi (hegyi.peter@pte.hu) or your treating physician.

I have read and understood the information, and I received appropriate answers to my questions. I received a copy of the prospectus.

Date: .....

Participant's signature:.....

Participant's name: .....

Signature of the doctor providing information:.....

Name of the doctor providing information: .....