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 **"ELEFANT"**, and for which we ask for your consent to participate.

Identification Data of the Study

Title of Research: **"Effect of early fatty acid elimination on the course of hypertriglyceridemia-induced acute pancreatitis (ELEFANT)"** (randomized, controlled clinical trial)

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 ethical approval (31.01.2025)**

Number of Participants to Be Included: **approx. 495 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: **2460-4/2020/EÜIG.**

The Purpose and Course of the Study

In this study, the institution's staff is recording data that may provide the first evidence of the need for early lipid-lowering interventions in patients with acute pancreatitis caused by high blood fat levels. The results obtained will not affect your treatment, but they may provide important new information to identify the factors influencing the success and effectiveness of treatment and may contribute to improving the outcome later.

Your doctor is conducting a randomized controlled trial on the treatment of acute pancreatitis due to high blood fat levels. During the study, we examine the development of your disease and any other genetic background.

From January 31, 2020, we ask for the consent of all patients with acute pancreatitis caused by high blood fat levels, so that we can record the results of the tests to be performed on the patients according to the regulations and guidelines that are in force at our clinic at all times and analyze them later.

Possible and Expected Consequences

The planned research has no effect on the diagnosis, treatment plan, and recovery time of your disease, it is completely independent of it, but it can provide important new information in the future both in regards to the

diagnosis, as well as the treatment of the disease. 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, you will not receive experimental treatment, and no examination will be conducted that is not already known in the field of gastroenterology, there is no specific risk 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: .....