PATIENT INFORMATION FOR CONTROL PARTICIPANTS

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

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Dear Sir/Madam, Dear Patient!

Please read this patient information in which we briefly summarized our research study Lifespan set up at the *Institute for Translational Medicine, University of Pécs*, *Hungary*, and in which we ask you to agree on participating as a member of the control group.

Title of study: Lifespan (**Lifespan: LIFES**tyle, **P**revention and Risk of **A**cute Pa**N**creatitis) (multicentre, prospective observational clinical study)"

Name, occupation and status of applicant: Prof. Dr. Peter Hegyi academic teacher

LIFESPAN is a multicentre, observational, case-control study which examines associations between socio-economic factors, dietary habits, physical activity, chronic stress, sleep quality and acute pancreatitis. In order to reveal these associations, we ask you to fill in a detailed questionnaire with the help of a clinical research administrator. Control group participants have no acute pancreatitis in medical history. Our aim is to find positive and negative associations, which gives the opportunity for the first time to provide concrete lifestyle advise, as well as help those who wish to prevent the development of the illness.

Within the framework of this study, associates of the (institution)……..... **collect data** anonymously. Through the study, the answers provided by you related to your risk factors, lifestyle, dietary, sleep and sport habits, socio-economic status will be recorded in the

database. The database will be analysed and assessed by different statistical methods. We do not plan to follow-up patients enrolled to the study, controll examinations will not be necessary.

We ask the consent of all newly diagnosed patients at the (institution)…… to record and subsequently analyse data gained from patient examinations according to protocols and professional regulations at all times.

The planned research study will not alter and is completely independent from either your diagnosis, treatment plan, time of recovery, however it may provide essential new information about associations regarding lifestyle concerning your illness, hereby the treatment as well. In relation to data collection you will not experience any inconvenience and no adverse event is to be expected.

Patients enrolled to the study do not recieve allowance for participating.

During the study medical history associated with your illness, answers concerning your lifestyle, dietary, sleep, sport habits and socio-economic circumstances will be recorded. We kindly ask you to fill in the forms with the help of a clinical research administrator. Filling in the questionnaires takes about 2 hours. After responding no further action is needed. The collected data are certainly handled according to medical confidentiality. In studies based on this research project data will be published without names and in an aggregated form, making impossible to deduce the identity of individuals. You will stay anonymous on every account.

We follow the current legislative acts concerning data protection.

Regarding data handling, you may make a complaint at the data protection supervisory authority, and in case of data breach you may go to court.

The ethical approval necessary for this research study has been issued by the Medical Research Council Ethics Committee, Hungary.

Certainly if you do not wish to participate in the research study, we do respect your decision and reassure you that it will not alter either your further medical treatment or the behaviour of our staff towards you.

You are free to inquire at the principle investigator of the study, whose contact information you will be informed about, about the process and results of the research project at any time.

Please do not hesitate to contact us with questions arisen in connection with the study.
Andrea Szentesi: szentesi.andrea.ildiko@med.u-szeged.hu

I have read and understood the patient information recieved appropriate answers for my questions.

A copy of the patient informationt sheet has been handed over to me.

_____

Signature of participant/legal representative

Date (signed) _____

Name of doctor providing information _____

Signature of doctor providing information _____

Date of information (signed)_____