INFORMATION SHEET FOR PARTICIPATION IN AN OBSERVATIONAL STUDY AND CONSENT DECLARATION FOR SUBJECTS WITH CAPACITY

Case group
Version 2.0 dated 16/04/2025

INFORMATION SHEET

Dear Madam/Sir,

A medical-scientific research study entitled "PRE-PDAC: Evaluation of the polygenic risk score for predicting the risk of pancreatic ductal adenocarcinoma: a case-control study" promoted by the Catholic University of the Sacred Heart in Rome is planned.

This research is national and multicenter in nature and aims to evaluate the role of polygenic risk in predicting pancreatic ductal adenocarcinoma.

In particular, the study will involve subjects affected by pancreatic ductal adenocarcinoma, such as yourself, and healthy subjects, with the aim of verifying whether among healthy subjects there are individuals at increased risk of developing this disease.

We need the collaboration and availability of people who, like you, meet the scientific requirements suitable for the assessment that will be carried out. However, before you decide whether to accept or refuse to participate, please read this document carefully, taking all the time you need, and ask us for clarification if you do not understand or need further details. In addition, if you wish, before deciding, you may ask for the opinion of your family members or your trusted physician.

PURPOSE OF THE STUDY

The study aims to collect detailed information on your personal and family history of cancer, your lifestyle, including habits such as smoking and alcohol consumption, any previous or ongoing medical conditions, previous surgical procedures involving the gastrointestinal tract, and the use of relevant drug therapies.

The main objective of the study is to analyze blood samples in order to evaluate the correlation between the polygenic risk score and predisposition to pancreatic ductal adenocarcinoma, with the aim of developing predictive models that may be useful for the prevention and management of the disease in the future.

WHAT YOUR PARTICIPATION IN THE STUDY INVOLVES

If you decide to participate in the study, you will only need to sign the informed consent form by which you will consent to the use of:

1. a portion of the blood sample already collected previously, in the period between April 2016 and September 2024, following your participation in a previous study. This sample will be used to evaluate the correlation between the polygenic risk score and pancreatic ductal adenocarcinoma. It will be your choice whether you wish to receive the results of these analyses. No further treatments or invasive tests are planned.
2. clinical information relating to your disease that has already been recorded in your medical chart (for example: age at cancer diagnosis, Ca19-9 and CEA levels, primary tumor location, histological grade, type of treatment received);
3. information previously collected through a questionnaire, including socio-demographic factors, lifestyle (such as smoking and alcohol consumption), anthropometric factors, personal and family history of selected diseases, use of selected drugs, and previous surgical procedures.

The study will last 24 months and will involve both healthy subjects, enrolled during routine visits at the Fondazione Policlinico Universitario A. Gemelli-IRCCS, and patients affected by pancreatic ductal adenocarcinoma, such as yourself, receiving treatment at the IRCCS San Raffaele Scientific Institute in Milan. A total of 570 patients and 570 healthy subjects will participate.

WHAT ARE THE RISKS ARISING FROM PARTICIPATION IN THE STUDY

Participation in the study does not involve any investigations or treatments other than those provided for in normal clinical practice; therefore, there will be no additional risks compared with routine clinical practice.

WHAT BENEFITS YOU MAY RECEIVE FROM PARTICIPATING IN THE STUDY

Participation in this study does not provide any direct benefit to you. However, it will allow us to better understand the impact of polygenic risk in the primary prevention of pancreatic ductal adenocarcinoma and to evaluate whether such risk may be an indicator in the prognosis of affected patients.

In particular, this study may be used to estimate the probability that an individual will develop pancreatic ductal adenocarcinoma, to stratify populations according to disease risk, and to identify those who may benefit from closer monitoring or preventive measures.

Your participation, therefore, will contribute significantly to scientific progress and may represent an advantage for other patients in the future.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

You are free not to participate in the study. In this case, you will in any event receive all standard therapies provided for your condition, without any penalty, and the doctors will continue to care for you with due attention.

INTERRUPTION OF THE STUDY

Your participation in this research program is entirely voluntary and you may withdraw from the study at any time by notifying the Investigator. In this case, the data collected up to the time of withdrawal will be considered in the results in aggregated and anonymous form for the final analysis.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you request it, at the end of the study you may be informed of the study results in general and, in particular, of those concerning you.

FURTHER INFORMATION

For further information and communications during the study, the following staff member will be available:

- Prof. Gabriele Capurso
Tel. 02.2643.5607
e-mail capurso.gabriele@hsr.it

The study protocol proposed to you has been reviewed and approved by the Territorial Ethics Committee (CET) Lazio Area 3. Among other things, the CET has verified the study's compliance with Good Clinical Practice standards and the ethical principles expressed in the Declaration of Helsinki, and that your safety, rights, and well-being have been protected.

Should you consider it appropriate to report events or facts relating to the study in which you have agreed to participate to persons not directly involved in the study itself, you may refer to the CET that approved the study.

CONSENT DECLARATION

(this declaration must be personally signed and dated by the patient and by the physician who conducted the informed consent discussion)

I DECLARE

☐ that I have received from Dr. _____ exhaustive explanations regarding the request to participate in the study in question, according to what is reported in the information section, of which I was previously given a copy forming part of this consent, and of which I was given a copy on _____

☐ that the nature, aims, procedures, expected benefits, risks, and possible inconveniences have been clearly explained to me and that I have understood them;

☐ that I had the opportunity to ask any questions to the study investigator and that I received satisfactory answers;

☐ that I had sufficient time to reflect on the information received;

☐ that I had sufficient time to discuss it with third parties;

☐ that I am aware that the research may be interrupted at any time;

☐ that I have been informed that the results of the study will be made known to the scientific community, protecting my identity in accordance with current privacy legislation;

☐ that I am aware that any choice expressed in this consent form may be revoked at any time and without any justification;

☐ that I have received a copy of this consent form.

Date _____
_____

Date	Patient's signature	Physician's signature informing the patient

(If the patient is unable to read or sign, a witness independent of the investigator and the sponsor must be present throughout the informed consent discussion. The witness must personally sign and date the informed consent declaration after the form itself and any other written information have been read and explained to the subject and the subject has verbally consented to participate in the study).

In this case:

I, the undersigned ……..., witness that Dr. …… has exhaustively explained to Mr./Ms. ……. the characteristics of the study in question, according to what is reported in the attached information sheet, and that he/she, having had the opportunity to ask all the questions deemed necessary, has freely agreed to participate in the study.

Date……. Signature of the independent witness ……..

Date……. Signature of the physician who provided the information to the patient …….