

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

Retrospective control group

Version 2.0 dated 18/12/2025

INFORMATION SHEET

Dear Madam/Sir,

At the Fondazione Policlinico Universitario A. Gemelli IRCCS, a medical-scientific research study entitled: “PRE-PDAC: Evaluation of the polygenic risk score for the prediction of pancreatic ductal adenocarcinoma risk: a case-control study”, promoted by the Catholic University of the Sacred Heart of Rome, is planned.

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

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

To carry out this research, we need the collaboration and willingness of people who, like you, meet the scientific requirements suitable for the evaluation that will be carried out.

However, before you make the decision to accept or refuse to participate, please read this document carefully, taking all the time necessary, and ask us for clarification should you not understand or should you need further details. In addition, should you wish, before deciding, you may ask your family members or your trusted physician for an opinion.

What the study aims to do

The study aims to collect detailed information on your personal and family history of cancers, your lifestyle, including habits such as smoking and alcohol consumption, any past or current medical conditions, previous surgical interventions on the gastrointestinal system, and the use of relevant drug therapies.

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

What your participation in the study entails

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

1. part of the blood sample already collected previously, in the period between February 2019 and February 2021, following your participation in a previous study. This sample will be used to assess the association 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 examinations are planned.
2. 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 interventions.

The study will last 24 months and will involve both healthy subjects, such as yourself, enrolled during routine visits at the Fondazione Policlinico Universitario A. Gemelli-IRCCS, and patients affected by pancreatic ductal adenocarcinoma 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 the performance of investigations or treatments different from those provided for in normal clinical practice and therefore there will be no additional risks in the study compared with clinical practice.

What benefits you may receive by participating in the study

Participation in this study does not entail direct benefits for you. However, it will allow us to better understand the impact of polygenic risk in the primary prevention of pancreatic ductal adenocarcinoma and to assess 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 nevertheless receive all the standard therapies provided for your condition, without any penalty, and the physicians will continue to follow you with the due standard of care.

Interruption of the study

Your participation in this research program is completely 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 the results of the study in general and, in particular, those concerning you may be communicated to you.

Further information

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

- Prof. Stefania Boccia
Tel. 0630154396
e-mail: stefania.boccia@unicatt.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 with the ethical principles set out in the Declaration of Helsinki, and that your safety, rights, and well-being have been protected.

Should you deem it appropriate to report events or facts relating to the study in which you have agreed to participate to parties not directly involved in the study itself, you may refer to the CET that approved the study (CET Lazio Area 3).

CONSENT DECLARATION

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

I DECLARE

- ☐ that I have received from Dr. _____ exhaustive explanations regarding the request to participate in the research 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 a copy was delivered to me on _____
- ☐ that the nature, purposes, procedures, expected benefits, risks, and possible inconveniences have been clearly explained to me and that I have understood them;
- ☐ that I have had the opportunity to ask any question whatsoever to the study investigator and that I have received satisfactory answers;
- ☐ that I have had sufficient time to reflect on the information received;
- ☐ that I have 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, while protecting my identity in accordance with the 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

Signature of the physician who informed the patient

(If the patient is unable to read or sign, an independent witness, separate from the investigator and the sponsor, must be present throughout the entire 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 expressed verbal consent to participate in the study).

In this case:

I, the undersigned, hereby attest that Dr.
..... has exhaustively explained to Mr./Ms.
.....

the characteristics of the study in question, according to what is reported in the information sheet attached hereto, and that the same person, having had the opportunity to ask all the questions he/she 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
.....