SHIELD Surveillance Program and sample collection – Informed Consent Form

Case subject – pancreatic cancer

1. Introduction

You are invited to participate in SHIELD, a 4-year European study funded by the European Commission, aiming to improve early detection of pancreatic cancer in individuals with an elevated risk because of genetic or familial reasons. This document will provide you with information about the study and what it means to participate.

2. Background: About Pancreatic Cancer and the SHIELD Project

Pancreatic cancer is one of the most serious forms of cancer. It is often diagnosed at a late stage because it usually does not cause symptoms early on. As a result, treatment options are limited and the survival rate is low.

The SHIELD study seeks to improve early detection of pancreatic cancer, especially among individuals at increased genetic or familial risk. Early detection is strongly linked to survival rate and crucial for surgical treatment. To validate new diagnostic tests, researchers need samples from individuals with a confirmed pancreatic cancer diagnosis. Your participation helps researchers better understand how to detect pancreatic cancer earlier and develop better tools for prevention and diagnosis. The research will investigate the differences in biomarkers between healthy individuals and patients with pancreatic cancer.

3. What Your Participation Involves

You will be asked to provide a single blood sample (no more than 20 ml, less than 2 tablespoons)
and
complete a brief questionnaire on your personal and family history of cancer.

This sample will be used to:

- Support the clinical performance validation of a blood-based test for early detection of pancreatic cancer
- Screen for known inherited genetic variants linked to pancreatic cancer
- Serve as a comparator in research on new biomarkers

This sample will be used in laboratory analyses to measure proteins and other biological markers associated with pancreatic cancer.

By joining this study, you may learn whether you carry an inherited genetic change that increases your risk of pancreatic cancer. If such a mutation is identified, your children and siblings may also be offered testing, as they could be at increased risk. In this study, we are screening for well-known inherited genetic variants linked to pancreatic cancer (e.g., mutations in *BRCA2*, *CDKN2A*, *STK11* genes, and others).

Your sample will be stored in a secure biobank and may be used in ethically approved research only in accordance with the scope of the consent you provide below.

Your participation supports research that may lead to the development of a simple blood test for early pancreatic cancer detection, potentially replacing the need for Magnetic Resonance Imaging (MRI) in the future. This could make screening more accessible for others at risk.

What It Means if a Genetic Mutation Is Found

You are being invited to participate in genetic testing. You can choose whether or not to participate and if you want to be informed of the result.

Because these mutations can be passed down, your close relatives (children, siblings, parents) may also be at risk. Sharing this information can be difficult. It may cause worry or stress in relatives but also gives them the opportunity to take part in surveillance or preventive care.

Finding a mutation means that you have a higher risk of developing cancer. Surveillance can help find cancer earlier, when treatment is more effective. In rare cases and depending on family history or combined cancer risks (e.g., breast, ovarian, melanoma), preventive surgery may be discussed, though this is not standard for pancreatic cancer. Some of the mutations also increase the risk of other cancers (e.g., BRCA1/2 and breast/ovarian cancer; CDKN2A and melanoma; Lynch syndrome genes and colorectal cancer).

4. What happens with my Data and Samples

As part of the SHIELD study, we will collect information about you from your electronic health record and from questionnaires. We will also collect a blood sample and possibly a buccal swab sample.

Your data and sample will be pseudonymised—this means your name and personal identification will be replaced with a secure code to protect your identity. The code key will be stored separately and securely at your local clinical site, and only authorized personnel will have access to it. No directly identifiable information about you will be shared with researchers or external collaborators.

Your blood sample will be sent to SHIELD biobank located at **Lund University Biomedical Centre, Sweden (136/BD-10)** for distribution to research defined in SHIELD, e.g. clinical validation and biomarker discovery, but also stored for use in ethically approved research on pancreatic cancer biomarkers. The sample will be used only in accordance with the scope of the consent you provide below. Research may include laboratory analyses in collaboration with European research institutions, any use beyond pancreatic cancer biomarker research would require renewed ethical approval and new consent. Research findings may contribute to the development of future diagnostic products.

Samples (blood sample or buccal swab) allocated for genetic testing will be shipped to Cyprus Institute of Neurology and genetics for analysis and destroyed after use.

Any **unused sample portions** will be retained for research purposes until the sample is exhausted. You may request the destruction of your samples at any time, and they will be securely destroyed in accordance with biobank regulations and institutional policies (See also section 7 on withdrawal from the study).

Your **pseudonymised data** (without any personally identifying information) will only be shared with partners, under a Joint Controllership Agreement (GDPR Art. 26), to support analysis and scientific publication.

Your local clinical investigator is responsible for your personal data, and for ensuring it is handled in compliance with **GDPR and ethical regulations**. You can exercise your GDPR rights against any Joint Controller.

5. Risks and Benefits

The risk involved in participation in the study is limited to potential minor inconvenience. Blood sampling may (rarely) cause pain, bleeding, bruising, or (very rarely) localised infection at the blood sampling site.

The psychological impact of learning if you carry a genetic risk will be addressed by access to counselling at your clinical site.

Benefits include the opportunity for your relatives to be included in screening and surveillance improving their chances of early cancer detection, and to contribute to pancreatic cancer research. In general, early detection of PDAC can significantly enhance survival rates and treatment outcomes.

6. Confidentiality

All information collected will be handled confidentially and in accordance with the General Data Protection Regulation (GDPR). Only pseudonymised data will be shared. The key linking your identity to the study ID will remain with your clinical site.

7. Voluntary Participation and Withdrawal

Participation is voluntary. You may decline or withdraw from the study at any time without affecting your healthcare. Data already analysed may lawfully be retained for scientific purposes (GDPR Art. 17(3)(d)), while unused samples and unprocessed data can be destroyed upon your request.

If you wish to withdraw your participation, you should contact the person responsible for the study (see section 10).

8. Compensation and cost

You will not incur any cost for participating in the study, nor will you be charged for any visits, consultations, examinations, or treatments specific to this study.

10. Contact Information

For questions about the study, your data or in case of withdrawal of consent, please contact your study physician or the SHIELD coordination team at:
[Insert local PI name, phone, and email]

This research had been approved by the ethics committee

11. Consent Statement

By signing this information and consent form, I hereby certify that:

- I have read this Informed Consent Form and have understood the information about the goal, benefits, implications, and risks of the study, the use of my body materials, its purpose, how it is carried out, and what is expected of me.
- I was given the opportunity to ask questions and received satisfactory answers. I have had enough time to calmly decide if I wanted to take part.
- I give my explicit consent to the processing of my personal data and use of my biological samples for the purpose of the SHIELD study, as stated herein.
- I agree that my samples and pseudonymised data may be used for ethically approved pancreatic cancer research and biomarker validation activities.
- I understand that I may withdraw from the study at any time without giving a reason, this includes asking to destroy my samples.

To give your free and explicit consent, please tick below:

☐ **I agree to share data and sample to evaluate if I carry genetic risk factors for pancreatic cancer**

☐ *I want to be informed if clinically relevant genetic findings are discovered.*
☐ *I do not want to be informed of any genetic findings.*

☐ **I agree to share data and samples for research purpose**

Participant Name: _____

Signature: _____

Date: _____

Participant ID:_____ (To be assigned by studyteam)

Study Physician/Nurse Name: _____

Signature: _____

Date: _____