



CONSENT FORM TEMPLATE

[TITLE OF PROJECT]

Background

We are asking you to take part in a research project on pancreatic cancer. Please read this information and ask any questions before you decide if you want to take part.

For this project, we will collect, store, and use pancreatic tissue samples and health information for research. These tissue samples concern the tumours in the pancreas as well as normal (healthy) tissue that may be removed during surgery. If you agree, your samples and some of your health information will be put into a biobank.

A biobank is a collection of samples and health information. Samples from many people are stored so they can be used for research now and in the future. Researchers apply to the biobank to ask for samples for their studies. If a study is approved, the biobank will give the researcher samples and information from many people. The biobank will not give researchers any information that could directly identify you, like your name or address. The researchers will then use the samples and information to learn more about pancreatic cancer.

Some researchers may use genetic analysis in some of the research they do on your samples. Studying genes along with health information will help us to better understand what causes pancreatic cancer. It may also help us to understand how different patients respond to treatment. This knowledge could help us to develop treatments for everyone.

Purpose

The purpose of this project is to collect pancreatic tissue samples and some health information. We will store these samples and information in a biobank so they can be used for research now and in the future. This research will help us understand more about pancreatic cancer.

Procedures

The research will be conducted at the following location(s): [LOCATIONS]

We will be collecting samples and information from people at the locations listed above. However, researchers from many different places may apply to study the samples and information stored in the biobank.

Where to samples come from?

Some pancreatic tissue may be removed after surgery or biopsy. This tissue could be discarded or destroyed because they are not necessary for your care; or, you may choose to let them be used for research.

We will only take this extra tissue if doing so will not significantly increase the risk to you.

What information will you collect?

Basic Information: We will ask you for some basic information. This will include things like name, age, sex, and race or ethnic group.

Clinical Information: We will collect information from your medical records that are related to your health and/or disease history. We may look at your medical record from time to time to update this information.

Who will have access to my samples and information?

We will store your samples and information in the biobank. We will remove your name and any other information that could directly identify you from your materials. We will replace this information with barcodes. We will keep a master list that links those barcodes to your materials. Only certain project staff can access this master list. We will keep the samples in locked freezers in locked buildings. We will keep health information and research data on secure computers. These computers have many levels of protection.

All of the samples and information will be labeled with barcodes. We will not share information that could directly identify you (like your name and address) without your permission.

There is no limit on the length of time we will store your samples and information. We may keep using them for research indefinitely unless you decide to withdraw from the project.

Potential Risks and Discomforts

Since the tissue we collect is left over from a procedure that is part of your clinical care, there are no additional physical risks to you if you take part in this project.

Will I be contacted in the future about this or other research?

We may want to contact you in the future. You can decide now whether or not you want to be contacted. You can also change your mind later.

If you agree, we may contact you to update basic information or request information about your health.

Additionally, we may want to contact you to see if you want to participate in other research. If at any time you decide you no longer want to be contacted about future studies, you can call [NAME] at [NUMBER].

How will my privacy be protected?

We will not give information that identifies you to anyone without your permission. This project takes many steps to protect the privacy of people who take part.

Research records are separate from medical records. We will not place any information from this project in your medical records.

Researchers who study your sample and information will not know who you are. We will give them only barcode numbers; we will not give them any information that directly identifies you. The researchers must sign an agreement that they will not access to your personal information.

Potential Benefits

You will receive no direct benefit from your participation in this project. However, your participation may help the investigators better understand how to prevent, detect, and treat pancreatic cancer in the future.

Subject withdrawal from a study

You have the right to stop participating in this project at any time. If you want to leave the project, call [NAME] at [NUMBER] to let us know.

You will be given some options and can choose what you want us to do with your unused samples. You can also tell us to stop using your medical records. However, you cannot withdraw your samples and information from studies that have already begun. We cannot get samples and information back once they are shared with other researchers. Also, it may not be possible to remove your genetic information from scientific databases once it has been distributed.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study (see above).

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Laws oblige us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

The investigator, [NAME], and/or someone he/she appoints in his/her place will try to answer all of your questions, even after the study is completed.

I agree with taking part in this study, as regards collection of samples and health information.

Yes _____ No _____ Initials _____

I agree that someone from this project may contact me in the future.

Yes _____ No _____ Initials _____