Thomas Jefferson University
Informed Consent Document for Human Subjects Research

Department: Surgery

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Medical Study Title: Jefferson Pancreas Tumor Registry (JPTR)

Lay Study Title: A research study looking for factors that may cause pancreatic cancer

What Is Informed Consent?

You are being asked to take part in a medical research study. Before you can make a knowledgeable decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before you sign this form;
- Being given a copy of your signed and dated consent form to keep for your own records.

You should understand that your relationship with the study doctor is different than your relationship with your treating or personal doctor. Your treating doctor treats your specific health problem with the goal of making you better. The study doctor treats all subjects according to a research plan to obtain information about the experimental drug, device or procedure being studied and with the understanding that you may or may not benefit from your participation in the study. You should ask questions of the study doctor if you want to know more about this.

What is the purpose of this study?

This is a research study. The Jefferson Pancreas Tumor Registry (JPTR) is attempting to collect information to determine if pancreas tumors and related conditions tend to occur more frequently in families with a history of the disease and to determine environmental and occupational risk

factors to which patients may be exposed. In this study, our aim is to gather information through the completion of the Jefferson Pancreas Tumor Registry questionnaire and to collect and analyze DNA samples that may find indicators or "biomarkers" of increased risk for pancreatic cancer. These samples may be obtained from patients undergoing pancreatic and other related cancer resections.

How many individuals will participate in the study and how long will the study last?
We hope to enroll over 100-200 patients each year. Enrollment is ongoing and will continue for many years.

What will I have to do during the study?
You will receive an annual JPTR newsletter and a short follow-up survey. The purpose of the annual survey is to monitor the course of your condition and to document the occurrence of new tumors or other conditions in yourself or in family members.

In some instances DNA samples will be screened for genes known to be associated with an increased risk of pancreatic cancer (these genes are called BRCA2, p16, PRSS1, hMLH1 and STK11). In some instances these DNA samples will be used to identify undiscovered genes associated with an increased risk of pancreatic cancer.

We may learn something in the future to suggest that you may benefit from gene testing. It is therefore possible that we may wish to contact you at a later time to make suggestions as to which gene test may be available to you from a clinical laboratory. If you do not wish to be contacted, check no below. If you do want to be re-contacted, it is up to you to make sure that we have your current address in our files. There are no risks associated with agreeing or not agreeing to be contacted in the future. There may be benefits however, because the identification of undiscovered genes associated with an increased risk of pancreatic cancer could make you aware of your potential vulnerability to the disease and allow further testing or screening. If you are asked to participate in another segment of this study, you will be consented and asked to review and identify factors that would influence your decision to register with the JPTR. These findings will be used to develop an improved decision support intervention for use in recruiting new patients to participate in the JPTR. This information may also be in conjunction with other studies that you may have consented to separately if you had your tumor removed at Jefferson, particularly the Jefferson Tumor Banking Study.

I want to know the result of testing if it will have an effect on my family.

☐Yes ☐ No (check one) Sign your initials here:_____

What are the risks or discomforts involved?
There is very little risk or discomfort associated with participation in this study. If undergoing surgery, you will not suffer any discomfort while collecting the samples, since you will be under

anesthesia as part of your surgical procedure. The tumor and tissue and fluid samples will also be collected at this time.

The completion of the initial questionnaire should take approximately 30 minutes. All information will be kept strictly confidential and will be used only for research purposes; however, there is a small risk of loss of confidentiality. This will be minimized in two ways: 1) No individual identifiers will be on laboratory data will be made publicly available, and 2) Data will be analyzed and reported for scientific and/or educational purposes as group data only.

Are there alternatives to being in the study?
The alternative to joining the study is to not participate in the Jefferson Pancreas Tumor Registry. If you decide not to participate, it will not affect your ability to receive medical care.

How will privacy and confidentiality (identity) be protected?
There are federal regulations about protecting information about you. This information is called "protected health information" (PHI). PHI includes things that identify you personally like your name, address and social security number, etc., or any medical of mental health record, or test result, such as an X-ray, that may have this sort of information on it. According to federal and state regulations, you may see your health information at any time. However, in a research study, you may not see the health information related to the research until after the research is completed unless the study doctor decides otherwise.

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study. Your PHI will also be shared, as necessary, with the University's Division of Human Subjects Protections and the Institutional Review Board (a University committee that reviews, approves and monitors research involving human subjects).

All of the above entities are obligated by law to protect your PHI.
If the results of the research are published or presented, your identity will remain confidential.
The following information will be provided to the study sponsor and other entities noted above.
Study Data for Analysis:

- Blood samples, as well as tissue, pancreatic juice and bile collected during surgery, if you had surgery at TJUH
- Medical records, including demographic data and clinical history will be accessed.
- JPTR questionnaire completed by the patient, family member or proxy respondent.

Your PHI will be used/disclosed:
[ ] until the end of the research study
[X] indefinitely.

You may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, in writing, at: Dr. Harish Lavu, Dept of Surgery, Suite 605 College Bldg., Thomas Jefferson University, 1025 Walnut Street, Philadelphia, PA 19107

If you quit the study further collection of your PHI will be stopped, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

What if I am injured as a result of being in this study?

In the event that you experience a research-related injury, comprehensive medical and/or surgical care (including hospitalization) to the extent needed and available will be provided. However, Thomas Jefferson University cannot assure that this comprehensive medical and/or surgical care will be provided without charge. The costs will be billed to your insurance carrier but they may ultimately be your responsibility. A research-related injury is a physical injury or illness resulting to you as a direct result of the experiments, treatment(s) and/or procedure(s) used in this study that are different from the medical treatment you would have received if you had not participated in this study. No other financial compensation is available.

Will I benefit from being in this study?

You and your family may or <u>may not</u> benefit directly from your participation in this study. However, although you may not benefit directly from this research, there may be a benefit to society, in general, from a better understanding of the risk factors for pancreatic cancer and increased knowledge of the occurrence of pancreas tumors in families. Any information obtained from this research study, and which may be important to your health or disease progression, will be shared with you. Additional benefits from your participation in this study may include:

1) Identification of risk factors for pancreas cancer,
2) Discovery of biomarkers that can be used in early detection of pancreas cancer and for screening high risk groups,
3) Identification of genes that may aid in individualizing treatment of pancreas cancer, as well as identifying new treatment strategies.

Will I be paid for being in this study?

You <u>will not</u> be paid for joining this study. There are no plans or resources to reimburse you for any problems that you may experience by being in this study.

Who should I contact with questions or if I think I have a research-related injury?

If you have any questions or concerns about this research, or if you experience a research-related injury, you may call the following numbers:

Telephone number for questions about your rights as a research participant	The Institutional Review Board	215-503-8966
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Harish Lavu, MD	215-955-9402
If you have difficulty contacting the study staff	Call the Institutional Review Board	215-503-0203

Will I be told about any new findings?

As the research progresses, any significant new finding(s), beneficial or otherwise, will be evaluated by the study director if it relates to the course of your treatment.

Are there costs related to being in this study?

Standard Testing Procedures

There should be no costs to the subject associated with this protocol. If you receive a bill that you think is wrong, please discuss it with the study doctor or research coordinator.

Voluntary Consent and Subject Withdrawal

You voluntarily consent to be in this research study. You have been told what being in this study will involve, including the possible risks and benefits.
You can agree to be in the study now and change your mind later. If you wish to stop, please tell us right away. If you leave the study early, Thomas Jefferson University may use any health information that it already has if the information is needed for this study or any follow-up activities.

If you decide not to participate in this investigation or withdraw your consent and discontinue participation in this study, it will not affect your ability to receive medical care at Thomas Jefferson University Hospital. If you withdraw from this study, you may continue treatment with your Jefferson doctor, or you may seek treatment from another doctor of your choice.

Your participation in this research study may be ended without your consent. Possible reasons for termination from the study include: not following study procedures as instructed, an event making your continued participation unsafe, or if the study has ended. There may be other reasons that end your participation without your consent.

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Non-Waiver of Legal Rights Statement

By your agreement/your permission to participate/allow your child to participate in this study, and by signing this consent form, you are not waiving any of your/ your or your child's legal rights.

In order to be in this research study, you must sign this consent/parental permission form.

You affirm that you have read this consent form. You have been told that you will receive a copy.

Signatures:

Your Name	Your Signature	Date
Name of **Person Conducting Consent Interview**	Signature of **Person Conducting Consent Interview**	Date
Name of **Investigator or Co-Investigator**	Signature of **Investigator or Co-Investigator**	Date

☐ **Copy of Signed and Dated Consent Form Given to the Subject**

Name of **Witness**	Signature of **Witness**	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

As per University Counsel - Do not sign this consent form after 10/19/17