

INFORMED CONSENT FOR CLINICAL RESEARCH

Interrogation of exosome-mediated intercellular signaling in patients with pancreatic cancer

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The purpose of this study is to isolate and analyze exosomes, which are tiny carriers of important proteins and nucleic acids that serve as messenger systems in the blood and tissue. Blood and tissue from patients with pancreatic cancer will be compared with blood and tissue from patients with noncancerous pancreatic disease. Including patients without cancer will allow us to establish “normal” values, which currently do not exist. We will then look to see whether exosome activity has a connection to disease recurrence and outcomes in patients. The results of this study will be the basis for future studies exploring this area.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because you have pancreatic disease and are scheduled to have surgery for this disease.

How many people will take part in the study?

About 70 people will take part in this study at MSKCC. 50 of these people will have pancreatic cancer, and 20 will have noncancerous disease.

What will happen if I take part in this research study?

Before you begin the study ...

You will have standard presurgical testing for your surgery. Depending on the tumor type you have or depending on your medical history, your doctors may want to perform additional tests. These tests will be only for your operation and are not related to your participation in this study. No additional tests will be done for this study.

During the study...

If you choose to take part, during your surgery:

- Blood will be drawn from a peripheral vein and the portal vein. The total amount of blood drawn will not exceed 45 milliliters (45 mL), or about 4 to 5 tablespoons. These samples will be processed and stored by our research staff and analyzed at a later date.
- Pancreatic fluid will be collected from the pancreatic duct.
- Three small biopsies (each about the size of a pea) of normal-appearing liver tissue will be taken.
- A biopsy sample of your tumor will be taken after it is removed.

First follow-up visit after your surgery (usually occurs 2 to 4 weeks after surgery):

- Blood will be drawn from a peripheral vein during your first follow-up visit, which will take place 2 to 4 weeks after surgery. This blood sample will be collected at the same time that your clinical liver function tests are performed. The total amount of extra blood collected will not exceed 10 milliliters (10 mL), or about 1 tablespoon.
- Your doctor will also assess if you have had any side effects following your surgery. This will be monitored up to 30 days after your surgery. This is part of your routine care and would be monitored if you were not on study as well.

After the study...

Once you have been transferred to the hospital room, usually the morning after your surgery, you will receive the same care you would if not in this study. You will be monitored and will have blood tests done until you are discharged from the hospital. This is the normal treatment for all patients who have had pancreas surgery.

How long will I be in the study?

You will be in the study for 30 days after your operation. Patients are usually in the hospital for 5 to 7 days after this type of operation. You will come back for your normal follow-up visit with your surgeon about 2 to 4 weeks after your surgery. You will have blood collected at that visit. After completing that visit, you will no longer actively be in the study and do not have to do anything further. All physician visits are part of your routine clinical care. We will track your progress using the MSKCC electronic medical record for life, but will not contact you directly.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or if you decide to stop.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

If you decide to stop at anytime, your standard follow-up care with your doctor will not change.

What side effects or risks can I expect from being in the study?

The risks of drawing blood from veins during surgery include:

Very Rare:

- Prolonged or late bleeding, possibly requiring blood transfusion
- Damage to the vein, requiring repair
- Blood clots and/or damage to the vessel

These side effects are very unlikely to occur. We know these side effects are rare because very few cases have been reported to happen during blood collection. As needles are not often used on the blood vessels around the pancreas, we do not know the exact rates of side effects for this type of blood collection. However, surgery on these vessels is very common, and the rates of side effects for this type of surgery are very low.

The risks of drawing peripheral blood include:

Less Likely:

- Bleeding at the site of blood collection
- Bruising at the site of blood collection
- Inflammation at the site of blood collection
- Blood clots and/or damage to the blood vessel

The risks of pancreatic duct fluid collection include:

Rare:

- Pancreatic duct injury
- Pancreatitis (inflammation of the pancreas)

The risks of liver biopsy include:

Less Likely:

- Prolonged or late bleeding at the site of the biopsy or internal bleeding

Are there benefits to taking part in the study?

Taking part in this study will have no direct benefit to you. We do know that the information gained from this study will help doctors learn more about exosomes and their activity in patients with cancer. This information may help future patients.

Will I receive the results from the study?

There will be no individual results from this study. The overall results will be used to try to improve the treatment of future patients.

Do I have to take part in this study?

You may choose to take part or not to take part in this study. Make your choice based on what we have explained to you and what you have read about the study. If you choose not to take part in this study, you will receive the same operation and treatment.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may be available at <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study. You are responsible for the usual costs of the operation you are having. These costs include physician visits, hospitalization, surgery, and imaging studies.

- You or your insurance provider will not be charged for the blood sample collection during your operation
- You or your insurance provider will not be additionally charged for liver and pancreas tissue taken and tested for research purposes only
- You will not be paid for taking part in this study

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose to take part or not to take part in this study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor, Dr. William Jarnagin, at 212-639-7601.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

A nonphysician whom you may call for more information about the consent process, to research patients' rights, or to research related injury is Jorge Capote, RN, Patient Representative. Telephone number: 212-639-8254.

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RESEARCH AUTHORIZATION

Research Participant Name: _____

Research Participant MRN : _____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group (which manages research databases), Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- Others:
 - The lab of Dr. David Lyden at Weill Cornell Medical College/Cornell University for specimen analysis

The following information will be used and/or disclosed for this research:

- Your entire research record.
- HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses, or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.

- HIV-related information collected during this study, if you choose to disclose it when talking to any of the staff
- Your medical records from the hospital.
- The following information: Blood, pancreatic fluid and tumor tissue

If you sign this form, it means you are giving us permission to share your protected health information. We can share it only with the people or organizations described above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also have the right to withdraw it at any time. If you withdraw it, we cannot use or share any more of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to Dr. William Jarnagin at the Department of Surgery/Hepatopancreatobiliary Service at Memorial Sloan Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights: 888-392-3644
- New York City Commission on Human Rights: 212-306-7500

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (LAR). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand.		
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A (Adult or Child <7)
Consenting Professional's Signature		Date:
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		Date:
Participant/LAR Name (Print)		
LAR Relationship to Participant		

<p>Witness Signature (If Required)</p> <p><input type="checkbox"/> Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).</p> <p><input type="checkbox"/> Other: I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.</p> <p>Name of Witness: _____</p> <p>Signature of Witness: _____ Date: _____</p>

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.