Consent Title: A Prospective Phase II Trial of Molecular Profiling to Guide Neoadjuvant Therapy for Resectable and Borderline Resectable Adenocarcinoma of the Pancreas

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EFFECTIVE

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MCW/FH IRB

Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

ENROLLMENT CONSENT

A Prospective Phase II Trial of Molecular Profiling to Guide Neoadjuvant Therapy for Resectable and Borderline Resectable Adenocarcinoma of the Pancreas

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You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, possible risks and benefits to you, your choices, and other important information. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are being invited to participate in the treatment phase of this research study because when you participated in the screening phase, the results of the laboratory test on your pancreas tumor provided information that your doctors will be able to use to decide what cancer treatment plan may be best for your type of tumor. This is called "personalized medicine" because the test may tell the doctor whether certain drugs are the best choice for treating your tumor.

A total of about 130 people are expected to participate in this study. Between 120 and 130 will be enrolled into the study at Froedtert and The Medical College of Wisconsin.

The Director of the study is Kathleen Christians, M.D.in the Department of surgery. A study team works with Dr. Christians. You can ask who these people are.

The funding source for this study is the Medical College of Wisconsin Department of Surgery "Pancreatic Cancer Research Program and Tissue Bank" through a grant awarded by the Advancing a Healthier Wisconsin program.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A research study is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

This study is being done to see if your doctors can use laboratory testing on your tumor to identify a treatment plan and increase the chance of successfully treating your cancer.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

STUDY PROCEDURES

Several extra tubes of blood (3 tablespoons) will be collected for future research at several points during the study.

All of the rest of the study procedures (except for the extra tubes of blood) are part of regular cancer care and may be done even if you do not join the study.

Procedures Prior to Treatment:

- Physical exam, including medical history
- Blood tests
- Pregnancy test for women of child-bearing potential
- Team review: A team of doctors review your information including information from your participation in the screening portion of the study and provide treatment recommendations.

Treatment Procedures:

- You will receive chemotherapy and/or chemo-radiation for 2-4 months prior to surgery, and for 4 months after surgery. You or your treating physician may be contacted by our research team periodically (as often as weekly) to ask how your treatment is going.

Study treatment will not continue if your cancer worsens—you will go off study and plan further treatment with your treatment team.

Restaging Between Treatments:

Periodically, you will have testing called restaging, to see how your tumor is responding to treatment

Restaging procedures include:

- Blood tests
- PET scan per physician discretion

- Chest X-ray or chest CT
- Contrast-enhanced CT scan and/or MRI of the abdomen (MRI's per physician discretion).
- For restaging after surgery only: laboratory testing of the pancreas tissue that is removed when you have surgery
- Appointment with the medical oncologist or the surgeon
- The team of doctors will discuss the findings of the tests and give their recommendations for continuing treatment.

As long as your tumor responds to treatment or stays the same, you will be restaged every few months. This restaging will occur:

- After each 2-month treatment
- 1-3 months after surgery
- Every 3 months for 18 months after study procedures are completed
- Then, every 6 months until you've been on study for a total of five years

If your cancer worsens you will go off study and the above procedures will no longer be required for the study. The study staff will contact you every six months to see how you are doing for the duration of the study.

RESEARCH PROCEDURES:
For the research study, the doctor will take a sample from the tumor removed during surgery for a special test. The test (which is called molecular analysis) may help us know more about the biology of your cancer and possibly guide the choice of drugs to treat the cancer. This is called "personalized medicine" because the test may tell the doctor which drugs may be a better choice for treating your specific tumor.

Should your cancer recur, your doctor may want to obtain a sample of tumor and conduct another molecular analysis to guide your therapy.

Several extra tubes of blood (about 3 tablespoons) may be collected at several points during the study.

TYPES OF TREATMENT
Chemotherapy:

- You will meet with a medical oncologist and his or her staff who will discuss the benefits and risks of chemotherapy in detail.
- The frequency and length of your chemotherapy treatments will depend on which type of chemotherapy is chosen.
- Your chemotherapy treatment may be given at Froedtert/MCW Clinical Cancer Center or at another cancer treatment location
- You will periodically have blood tests and a medical exam during your chemotherapy treatments.
- After about 2 months of treatment, you will be restaged.

Chemo-radiation:

- At some point in your treatment you will receive radiation therapy combined with chemotherapy.
- This may occur either before or after surgery.
- A radiation oncologist will meet with you and explain the risks/benefits of receiving radiation therapy combined with chemotherapy.
- Your chemo-radiation treatment may be given at Froedtert/MCW Clinical Cancer Center or at another cancer treatment location
- After about 2 months of treatment, you will be restaged.

Surgery:

You will have surgery about 1 month after completing 2-4 months of chemotherapy and/or chemo-radiation.

- Your surgery will be done at Froedtert/MCW Clinical Cancer Center.
- The sample of the tumor will also be examined in the laboratory to see if there have been any changes in the tumor compared to the sample that was taken in the screening phase of this study. The doctor may use this information to direct your treatment plan after surgery.
- Tumor cells also will be transplanted into experimental mice to grow the cells and find out more information about how the tumor grows and how it might be treated.
- You will have standard visits with your surgeon after your surgery.
- 1-3 months after surgery, you will be restaged as outlined above and your next treatment will be determined by the study review team.

B2. HOW LONG WILL I BE IN THE STUDY?

You will be in this research study for up to 5 years.

B3. CAN I STOP BEING IN THE STUDY?

You are free to withdraw from the study at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the study doctor. The doctor can tell you about the effects of stopping, and you and the doctor can talk about what follow-up care would help you the most. You might be asked to come back for one more visit to check your health.

The study doctor may take you out of this study at any time. This would happen if:

- The doctor thinks it is in your best interest.
- You do not follow the study rules.
- The whole study is stopped.

If this happens, the study doctor will tell you.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE STUDY?

Although the chemotherapy offered in this study is the standard of care, you need to let your study doctor know if you are taking any new medications during the study.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

All of the drugs used in this study are approved by the FDA for pancreas cancer. However, there are risks to taking part in any research study. There is a risk that this may not help your condition or may make it worse. If we learn about new important side effects, we will tell you.

We watch everyone in the study for problems (side effects). You need to tell the study doctor or a member of the study team immediately if you experience any problems, side effects, or changes in your health.

C2. RISKS OF THIS STUDY

The risks of this study are the same as for standard chemotherapy, chemo-radiation therapy and surgery. Because we are using the standard therapies in this study, the only additional risk is the minimal risk involved in drawing extra blood on the first day that you enroll in the study.

Risks of standard chemotherapy, chemo-radiation and surgery:

Chemotherapy, radiation and surgery cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away. Many go away soon after the treatment is stopped. Drugs and interventions can affect individuals in different ways. Your study doctors will discuss with you the possible side effects of chemotherapy, surgery and radiation before you undergo the treatment.

C3. OTHER RISKS OF THIS RESEARCH STUDY

Other procedures that are part of the study also involve some risks, but they are part of your stancard care for cancer and will be explained to you as needed.

C4. REPRODUCTIVE RISKS

Birth control methods for all subjects

Check with the study doctor about the birth control methods needed for this study and how long to use them. Some methods might not be good enough for this study. If you are having sex that could lead to pregnancy, you should use birth control while you are in this study.

This may include:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Surgical sterilization (hysterectomy or tubal ligation)
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of diaphragm with condoms (“double barrier”)
- Limiting sexual activity to a male partner who has had a vasectomy

You should be using appropriate birth control 4 weeks prior to Day 1 of treatment and continue using birth control for 4 months after stopping the treatment.

Risks to women who could become pregnant
We know that the drugs and procedures used in this study might affect a baby, before or after the baby is born. You should not become pregnant or nurse a baby while in this study. You must tell the study doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the study and prior to surgery.

Risks of fathering a child
You should not father a baby while taking part in this study because drugs / interventions in this study could affect a baby. If your partner is able to become pregnant, one or both of you must use some form of effective birth control. You must tell the study doctor right away if you think your partner is pregnant.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY

This study may or may not help you. A benefit of participating in the study is that your doctors may identify a more effective chemotherapy treatment plan and this may increase the chance of successful surgical removal of the tumor if you have surgery. We hope the information from this study will help us gain information that may help patients in the future.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

Your medical care is considered routine care for your condition and would be recommended whether you join the study or not. Costs for routine care will be billed to you or your insurance carrier. Some insurers will not pay for drugs, tests or hospitalization that are part of research studies, so check with your insurer before you undergo the procedures. Activities/costs that are research (and not routine care) will NOT be billed to you or your insurance company. These include research testing of the surgical sample. If you have questions regarding study costs, please contact Dr. Christians.

D2. WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

There is no payment for being in this study.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. If you do not join this study, your doctor can discuss other healthcare choices with you.
Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment
- Getting comfort care only, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important new information that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D5. WHAT HAPPENS IF I AM HARMED BECAUSE I TOOK PART IN THE STUDY?

No funds have been set aside to pay any costs if you become ill or are harmed because of this study. If you think that you have become ill or were harmed because of this study, let the study doctors know right away by calling 414-805-9720. By signing this form, you do not give up your right to seek payment for harm you receive while participating in this study.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If you have more questions about this study at any time, you can call Dr Christians at 414-805-9720.
- If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-456-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To do this research study, we need your permission to collect and use some of your health information, or you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

The health information to be collected and used for this study is:

- Medical records of the care you receive for this study
- Medical records dating from when you join this study and ongoing
- Medical records, scans or biopsies taken when you were first diagnosed with pancreas cancer

E2. Who will see the health information collected for this study?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the study team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow

to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different study without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?
One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study doctor about whether this could apply to you.

E4. How long will you keep the health information for this study?
If you sign this form, we plan to keep your information 10 years after the study ends in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Christians at Department of Surgery, Froedtert Hospital, 9200 W. Wisconsin Ave.Milwaukee, WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

F1. FOR MORE INFORMATION ABOUT THE STUDY

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. 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.

You can look up this study by referring to the ClinicalTrials.gov number NCT01726582 or by asking the study team for a printed copy.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Legally Authorized Representative (if applicable**)** *please print*	**Signature of Legally Authorized Representative**	**Date**
Name of Witness (if applicable**)** *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date**
*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**