DEPARTMENT OF RADIATION ONCOLOGY

WILMOT CANCER CENTER

UNIVERSITY of ROCHESTER MEDICAL CENTER

Yuhchyau Chen, M.D. Ph.D.
Professor and Chair of Radiation Oncology

CONSENT FORM

Title of Study: PILOT STUDY OF SHORT-COURSE PREOPERATIVE STEREOTACTIC BODY RADIATION THERAPY FOR RESECTABLE PANCREATIC CANCER

Principal Investigator: Alan Katz, MD MPH

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you have pancreatic cancer that can be removed by having surgery (surgically resected).

This study is being conducted by Alan Katz, MD MPH of the University of Rochester's Department of Radiation Oncology.

Purpose of Study

The purpose of this study is to determine if treating your pancreatic cancer with a special kind of radiation therapy called stereotactic body radiation therapy (SBRT) before you have surgery is safe and feasible. Standard treatment for newly diagnosed pancreatic cancer determined to be resectable usually involves undergoing surgery first and then receiving chemotherapy with or without

radiation therapy. However, the pancreatic cancer often comes back after this treatment.

Description of Study Procedures

If you decide to take part in this study, you will be scheduled to meet with a radiation oncologist, a specialist in using radiation to treat cancer. Your radiation oncologist will go over this protocol with you and answer any questions you may have. You may need to undergo additional blood work or scans such as CT, MRI or PET to make certain that you meet the criteria for this study. Most of these tests are a routine part of your care. In general, they do not need to be repeated if they have already been completed as part of your diagnostic workup.

If your doctor feels it will be helpful to your treatment you may be asked to undergo endoscopic placement of “fiducials” or markers into your pancreatic tumor, which will be used to help guide radiation therapy.
Regardless of whether you receive fiducials you will need to undergo a “simulation” procedure for radiation therapy which involves a CT scan in the department of radiation oncology to help map out the radiation. IV contrast may be given during the CT scan to help better visualize the tumor; the radiation oncology doctor will decide if contrast is necessary.

Approximately 1-2 weeks after you undergo simulation, you will return to the Department of Radiation Oncology for SBRT radiation treatment. You will receive 5 treatments delivered over a 1-2 week period. Each session lasts approximately 30-45 minutes.

Within 3 weeks after you complete your radiation treatment, you are expected to undergo surgery to remove your pancreatic cancer. After your surgery, you will return for a follow up visit with your surgeon and radiation oncologist to evaluate how well you are doing and go over any side effects you may have experienced.

Number of Subjects

We expect approximately 18 subjects to participate in the study.

Duration of the Study

Your participation in the study will last approximately 5 years. You will undergo diagnostic workup and treatment during the first 1-2 months followed by routine follow up visits for 5 years.

Risks of Participation

This study is being conducted because your doctors think that treating pancreatic cancer with preoperative SBRT may improve your outcome compared with standard treatment. There have been several small studies at other institutions which have shown delivering SBRT to the pancreas is safe and effective. However, there is no way to tell in advance whether treatment according to this

study will in fact be beneficial. In fact, your doctors may find that treatment according to the study might not be beneficial and could even harm participants.

Specifically, delivering SBRT prior to surgical resection could cause side effects that could hamper or delay your surgery, which is the most important treatment for your disease. However, previous studies have demonstrated that the vast majority of patients who undergo preoperative radiation can safely undergo surgery in a timely fashion.

Radiation therapy can cause both acute and delayed side effects. Acute side effects that take place during or immediately after treatment can include fatigue, nausea, vomiting, diarrhea, loss of appetite and weight loss. These effects are expected to be mild and can be managed with supportive care like anti-nausea or anti-diarrheal medicines. Delayed side effects can take place months to years after radiation and can include delayed wound healing, scar tissue formation and bowel obstruction and narrowing. These effects are expected to be very rare.

There is a risk of invasion of your privacy. All the information gathered from your chart or records, including your name and any other identifying information will be kept strictly confidential and will be kept under lock and key. You will not be identified nor will any information that would make it possible for anyone to identify you be used in any presentation or written reports about this study. Only summarized data will be presented at meetings or in any publications.

Summary of Risks:

Common (usually lasts only 1-2 weeks following radiation)

- Nausea
- Loose bowel movements
- Fatigue

Uncommon

- Loss of appetite
- Vomiting
- Dehydration / weight Loss

Rare

- Complications leading to delay or cancellation of surgery
- Increased fibrosis leading to increased operating time or blood loss during surgery
- Increased post-operative complications such as delayed wound healing or leakage from your re-attached bowels
- Bowel perforation, ulceration or narrowing several months following radiation

Benefits of Participation
You might not benefit from being in this research study. The potential benefits to you from being in this study include:

- There might be a higher chance of controlling your cancer compared with standard treatment
- There might be fewer side effects compared with standard treatment
- You will spend less time receiving radiation compared with standard treatment

New Study Findings
If we discover anything that might make you change your mind about continuing in the study, we will let you know.

Alternatives to Participation
If you decide not to participate in the study, you can choose to receive the standard treatment for pancreatic cancer as determined by your physicians. In addition, you can choose to receive no treatment for your cancer or only palliative treatments that are designed to alleviate symptoms.

Costs
Some of the tests/procedures/exams such as CT scans and the surgery to remove your tumor are standard care. You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You and/or your insurance company will also be responsible for paying for the SBRT radiation that you will receive as part of this study. As usual, we will attempt to obtain prior authorization for your radiation treatment from your insurance provider. If there are any difficulties obtaining this we will discuss it with you prior to your treatment. You are encouraged to discuss your coverage with your insurance provider.

Payments
You will not be paid for participating in this study.

Circumstances for Dismissal
You may be withdrawn from the study if you do not keep appointments for study visits or if you cannot complete study activities. You may also be withdrawn from the study if your cancer becomes worse or if your doctor feels that staying in the study is harmful to your health.

Early Termination
You may decide to stop participating in the study at any time. You should tell your study doctor as soon as possible so that he or she can explain to you the risks associated with stopping the study. For example, if you choose to stop radiation after beginning treatment, you may be exposed to the side effects of

radiation treatment without the expected benefit. Even if you decide to stop participating, your doctors will continue to give you the best treatment possible.

Compensation for Injury

If you are directly injured by the SBRT radiation that is being studied, or by the clinical procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. As soon as feasible, any information that can identify you such as your name and date of birth will be erased from the study database. Only your medical record number will be used to identify your participation in the study. All the information gathered from your chart or records will be kept under lock and key.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Alan Katz, MD MPH at (585) 275-3913

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Signature/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date