RESEARCH CONSENT FORM

You are being asked to participate as a subject in the research project entitled, "Las ablation of localized prostate cancer" under the direction of Eric Walser MD and Jose Sonstein MD. This project will be supported by internal Department of Radiology funds and UTMB.

PURPOSE OF THE STUDY

The prostate gland is a sexual organ that lies between the bladder and penis and is important in carrying sperm from the testicles to the penis during ejaculation. When the prostate is affected by cancer, usually surgery, radiation or hormone treatments are needed to treat the entire prostate. There are bad side effects from these treatments including incontinence (leaking urine) or impotence (unable to have erections) or damage to the rectum. Laser ablation is a new treatment that treats only the visible prostate cancer so that damage to nerves, blood vessels and other organs near the prostate is avoided. We can treat prostate cancer this way today because of new, more powerful magnetic resonance imaging (MRI) scanners which allow your doctors to see the prostate gland much more clearly. Now, like in mammograms, we can see "spots" of prostate cancer on MRI very early, when the tumors are only ½ inch in diameter. Since we can see these tumors, we can heat just the tumor with a laser fiber and kill the cancer but spare the rest of the prostate gland and surrounding structures. However, we are still not sure how well laser ablation controls cancer in the rest of the prostate and, although we think the side effects are much less than prostate removal, we need to prove that by watching how patients do after this procedure.

You are a candidate for this study since you recently had laser ablation of your prostate tumor. The risks, benefits and alternative treatments for the laser treatment were explained to you in a separate consent form. The following consent is to allow us to follow up on your MRI studies, blood tests and general health over the next two years.

PROCEDURES RELATED TO RESEARCH

As a patient, you previously had laser ablation as treatment for localized prostate cancer. This study is research into the effectiveness of laser ablation and is conducted by gathering your medical records for two years after the ablation. We will monitor your prostate by blood tests and MRI and by physical exam 6 months, 1 and 2 years after the procedures is completed. If at any time, a new tumor appears in your prostate, we will discuss this with you and your other doctors and you may have another biopsy. If there is new prostate cancer after the laser ablation, you may undergo repeat ablation, surgery, radiation therapy or drug treatment- depending on your doctors recommendations and your preferences.

Exclusions

You should not participate in this study if:

1) You are under 21 years old
2) Your blood does not clot normally
3) Your kidney function is diminished
4) You cannot give an informed consent
5) You have evidence of metastatic disease (cancer outside of the prostate gland)

RISKS OF PARTICIPATION

The risks of participating in this study only involve the rare occurrence of your private health information being revealed. We carefully protect this data in secure digital files identified by your medical record number and not your name. Therefore this risk is minimized as much as possible.

NUMBER OF SUBJECTS PARTICIPATING AND THE DURATION OF YOUR PARTICIPATION

The total number of anticipated subjects involved in the study at UTMB will be 30. The length of time for your participation is 2 years with a minimum of 3 visits.

BENEFITS TO THE SUBJECT

You may not receive any direct benefit from your participation in this research. The potential benefit to you may be improved evaluation of your prostate.

BENEFITS TO THE SOCIETY

This study may provide benefits to society in general since it may allow us to better treat prostate cancer with fewer side effects.

OTHER CHOICES (ALTERNATIVE TREATMENT)

You have the option of not participating in this study. You will still undergo clinical follow up over two years, but we will not include your data in our research. Your health care will be the same whether you participate in this study or not.

SAFE WITHDRAWAL FROM THE STUDY

Your decision to withdraw from the research procedure will not delay or impede your medical care.

REIMBURSEMENT FOR EXPENSES

You will not be reimbursed for participation in this study.

COSTS OF PARTICIPATION

None

REASONS FOR THE STUDY INVESTIGATOR TO STOP YOUR PARTICIPATION

The investigators may stop your participation at any time. The reason could be lack of subject compliance with the study requirements, adverse events or other situations where your safety and well-being may be affected or because the whole study has been stopped by some unpredictable conditions.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION

Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provides safeguards for privacy, security, and authorized access of your records. These regulations require UTMB to obtain an authorization from you for the use and disclosure of your health information. By signing this consent form, you are authorizing the use and disclosure of your health information for the purpose of completing the research study. Except when required by law, you will not be identified by name, social security number, address, telephone number or any other direct personal

identifier in study records disclosed outside of the University of Texas Medical Branch (UTMB). For records disclosed outside of UTMB, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Walser 's office.

Study data may be disclosed to third parties involved in medical research and publication. While these people may understand the importance of protecting the confidentiality of your health information, UTMB cannot guarantee the confidentiality of your health information or protect from further disclosures once these recipients receive your health information.

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. We can only do the research if we are allowed to collect, use and share your health information. Whether or not you agree to the research project or give us permission to collect, use or share your health information will not affect the care you will be given at UTMB.

Dr. Walser will use and disclose your study related information. This will include laboratory tests, biopsy results x-rays, CT scans or MRI. These tests have been done as part of your regular care. These test results will be recorded in your medical record. You may see or receive a copy of any research information that will be included in your medical record. For all other health information we collect on you that will not be included in your medical record, you may not be allowed to access or receive a copy of the information until the conclusion of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include, for example, the Food and Drug Administration, UTMB and UTMB IRB. This authorization for the use and disclosure of your health information as described above expires upon the conclusion of the research study except for FDA regulated studies. For FDA regulated studies, the study sponsor and government agencies, such as the FDA may review your records after the study ends.

If you change your mind later and do not want us to collect or share your health information, you need to contact the researcher listed on the attached consent form in writing. You need to say that you have changed your mind and do not want the researcher to collect and share your health information. You also may need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it. The results of this study may be published in scientific journals without identifying you by name.

ADDITIONAL INFORMATION

1. If you have any questions, concerns or complaints before, during or after the research study or if you need to report a research related injury or adverse reaction (bad side effect), you should immediately contact Dr. Walser at 409-747-0100 or Jackie Aoughsten ARNP at 409-772-9209.

2. Your participation in this study is completely voluntary and you have been told that you may refuse to participate or stop your participation in this project at any time without penalty or loss of benefits and without jeopardizing your medical care at UTMB. If you decide to stop your participation in this project and revoke your authorization for the use and disclosure of your health information, UTMB may continue to use and disclose your health information in some instances. This would include any health information that was used or disclosed prior to your decision to stop participation and needed in order to maintain the integrity of the research study. If there are significant new findings or we get any information that might change your mind about participating, we will give you the information and allow you to reconsider whether or not to continue.

3. If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information, you may contact the Institutional Review Board Office, at (409) 266-9475.

The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been allowed to ask questions and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. You have read this consent form and voluntarily agree to participate as a subject in this study. You are free to withdraw your consent, including your authorization for the use and disclosure of your health information, at any time. You may withdraw your consent by notifying Dr. Walser at 409-747-0100. You will be given a copy of the consent form you have signed.

Informed consent is required of all persons in this project. Whether or not you provide a signed informed consent for this research study will have no effect on your current or future relationship with UTMB.

Signature of Subject	**Date**

Name of Subject	**Date**	**Subject Unit History number**

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject

Signature of Person Obtaining Consent	**Name of Person Obtaining Consent**

Date