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UTMB FORMS MGT. STRICTLY PROHIBITS CHANGES TO THIS FORM

I voluntarily request Dr. Eric Walser, as my physician, and such associates, technical assistants, and other health care providers as may deem necessary, to perform magnetic resonance thermal image-guided laser-induced interstitial thermal therapy for focal ablation of prostate cancer. This procedure has been explained to me as a minimally invasive alternative to active surveillance, radical prostatectomy, radiation therapy and brachytherapy for the treatment of prostate cancer. Laser ablation is a targeted procedure that focuses on a single area of tumor as opposed to whole-gland therapy.

I understand that during the procedure a laser applicator is introduced under MRI-guidance via the rectum. Once in the gland, a non-therapeutic "test" dose is administered to verify proper placement in the target, the dose will be increased and the physician will observe activity "real time" on a thermal map. Once the entire area is treated (1-2 minutes), the laser is turned off. One or more ablations may be performed depending on the size, number or shape of the tumors.

Just as there may be risks and hazards continuing in my present condition without treatment, there are also risks and hazards related to the performance of MR guided laser ablation. I understand that all procedures, regardless of complexity or time, can be associated with unforeseen problems, which may be immediate or delayed. My physician discussed with me and I understand that the following risks and hazards may occur in connection with MR guided laser ablation:

- Excessive Bleeding from the Rectum/Anus: It is uncommon that such bleeding requires any treatment, and in the majority of cases bleeding stops on its own. This is far more common in patients with hemorrhoids.
- Blood Clots in the Urine: The device can enter the middle of the prostate where the urethra or the neck of the bladder are located and cause blood in the urine. If the bleeding is significant, it can cause clots that can block the urine flow. A urinary catheter may need to be inserted to flush out the clots.
- Urinary Retention: Even in the absence of bleeding, the prostate can become swollen from the treatment or secondary to infection. In this instance, a catheter is placed and your physician will discuss the next step. Usually, the problem resolves with time after the swelling goes down. Sometimes, medications are given that may help to open the prostate channel. Patients at greater risk are those who already have difficulty urinating before the procedure due to BPH (Benign Prostatic Hyperplasia).
- Urinary Tract Infection or Urosepsis: Although you will be prescribed antibiotics, it is possible for you to get an infection. It might be a simple bladder infection that presents with symptoms of burning urination, urinary frequency and a strong urge to urinate. This will usually resolve in a few days with antibiotics. If the infection enters the bloodstream, you may feel very ill. This type of infection often presents with the urinary symptoms and any combination of the following: fevers, shaking, chills, weakness or dizziness, nausea and vomiting. You may need a short hospitalization for intravenous antibiotics, fluids, and observation. This is more common in diabetic patients, patients on long-term steroids, or patients with any disorder of the immune system. Lastly, an abscess of the prostate, while quite rare, can develop. This is an infection cavity that may respond to antibiotics alone or need surgical (needle) drainage. It can begin with urinary symptoms but also progress to the symptoms of bloodstream infection. Urinary retention is possible with an abscess.
- Erectile Dysfunction (ED): Inability to achieve or maintain an erection can occur following this procedure in less than 10% of patients. This condition may be temporary or permanent.
- Urinary Incontinence: In less than 5% of men undergoing this procedures, the ability to voluntarily control urination may be lost. This may be a temporary or permanent condition.
- Numbness of the Penis: Some men may lose some or all sensation in their penis following the procedure. This condition usually resolves over weeks to months.
- Rectal Fistula: Rarely, an abnormal communication between the rectum and the urethra or urinary bladder may develop. Treatment of this condition may require surgery.
- Residual Prostate Cancer: Several studies have shown that there is improved survival after ten years following whole-gland definitive therapy (radical prostatectomy, radiation therapy) compared with active surveillance (watchful waiting) for the treatment of prostate cancer confined to the prostate gland. No similar studies currently exist confirming improved survival following laser focal ablation of the prostate gland for prostate cancer.

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IF PATIENT ID CARD OR LABEL IS UNAVAILABLE, WRITE DATE, PT NAME AND UH# IN SPACE BELOW

**MAGNETIC RESONANCE GUIDED
LASER ABLATION INFORMED CONSENT**

Radiology

Medical Record Form 8092-12/15 (Page 2 of 2)
**The University of Texas Medical Branch Hospitals
Galveston, Texas**

Original-Medical Record

If you develop any of the symptom above, especially those of infection, contact the office of Dr. Eric Walser (409) 747-0100 immediately or go to the nearest emergency room.

I have been given the opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedure to be used, and the risks and hazards involved. I believe that I have sufficient information to give my informed consent.

I certify that this form has been fully explained to me, that I have read it or have had it read to me, and that I understand its contents.

By signing this Informed Consent, I agree to have magnetic resonance thermal image-guided laser-induced interstitial thermal therapy for focal ablation of prostate cancer.

Physician

Date

Time

Patient

Date

Time

Witness

Date

Time