Informed Consent

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MRI Guided Prostate Cancer Focal Laser Ablation
Principal Investigator Sherif G. Nour, MD, FRCR

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You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Magnetic Resonance Imaging (MRI) Guided Focal Laser interstitial thermal Ablation of Localized Prostate cancer: A Phase II Clinical trial

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Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

Background:

Prostate cancer is the most common cancer (other than skin cancer) in American men, with 1 in 7 men being diagnosed with this disease during his lifetime. The American Cancer Society expected the number of new prostate cancer cases in 2017 to be 161,360. With 26,730 expected deaths from this disease during the same year, prostate cancer is the second deadliest cancer in American men after lung cancer.

Prostate cancer has different levels of grades, ranging from a very low-risk process to an aggressive high-risk potentially fatal disease. The possibility that a “true” low-risk prostate cancer advances to metastatic disease is very small. Much more likely, a high-risk cancer has been present and undetected from the beginning.

Over the past years, doctors have been concerned that patients with true low-risk prostate cancer are being over treated. Many studies showed that there is no benefit from aggressive treatment of the whole prostate gland, such as with surgery or radiation, in patients with low-risk prostate cancer. A large study showed that 55% of 24,405 patients treated for low-risk prostate cancer in the United States have received unnecessary aggressive treatment. The problem with aggressive treatment is that too many patients end up with serious life-changing complications such as losing control on their urination or defecation or losing the ability for erection. These patients could have a better quality of life with less aggressive treatment while receiving no less care for their cancers.

Another way to handle low-risk prostate cancer and avoid these complications is to choose to just watch it (also called active surveillance). The problem with this choice is that it is difficult for some people to have a normal daily life when they know they have untreated cancer in their body. It also may be too late for treatment if cancer spreads while being watched.

Because it is difficult to choose between going for aggressive treatment with high risk for complications and choosing not treat at all, doctors are now experimenting a new treatment where they only destroy the area of cancer and leave the rest of the prostate unharmed. They want to see if this method will have less complications than aggressive whole gland treatments (such as surgery or radiation). They also want to see if cancer will be really well-controlled with this treatment.

Purpose:
The purpose of this study is to evaluate the use of laser fibers to burn localized prostate cancers under MRI guidance. We need to know how effective it is in killing the tumor and how it may affect urinary and rectal continence and erectile function. We will enroll 20 patients with localized prostate cancer visible on MRI. Tumors will be burnt using an FDA-approved laser device (Visualase, Medtronic, USA). Patients will be followed up for 2 years to see if tumor is completely treated and to see the effect of treatment on urinary and rectal continence and erectile function.

What will I be asked to do?
Before procedure:
You will be asked to have blood test (about 5 mL, equivalent to a teaspoon full) to determine your pre-treatment baseline of your tumor marker (serum PSA level) so we can monitor your disease on follow ups. We will also test the ability of your blood to normally form a clot after puncturing the prostate gland to avoid serious bleeding.

Procedure:
Before coming to the hospital, you will be requested to take oral antibiotics and oral urinary tract pain killers. If you are taking blood thinners, you will be requested to stop them 5 days before the procedure (please check with your treating physician). An overnight fasting for 8 hours is required prior to the procedure. On the morning of the procedure you will have a Fleet enema.
When you arrive at the hospital, a catheter will be inserted to protect the urethra.

In the procedure room, you will have general anesthesia (you will be totally asleep with no feeling of the surrounding) and will be put to sleep on your belly inside the MRI scanner. After lesion identification, a laser fiber will be inserted into your prostate under MRI guidance, either through your rectum or your buttocks and ablation (the tumor burning procedure) will be monitored using real time temperature maps to ensure appropriate and safe ablation. Afterwards, MRI scan will be done to serve as a baseline for follow up. The catheter will remain for 3 days and will be removed in the radiology department or at your local urologist office if you live far away or if this is your preference.

You are expected to participate in a long-term follow up process. Follow ups in person clinic visits will be scheduled at 3 weeks, 3 months, 6 months, one year and two years. Each follow up time point is calculated from the previous visit, not from procedure date. In each visit, you will have a MRI, serum PSA, fill forms to assess your urinary continence and erectile function, and if applicable, discuss an MRI guided biopsy, which would be done on a different date.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information are used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are: irritation of the urethra, catheter discomfort, mild bleeding in urine or stools (in a previous similar study reported rates were between 8-15 %)

The less common risks and discomforts expected in this study are: infection, Urinary tract obstruction, abnormal erection, and urine or fecal incontinence (losing control of urine and stool).

Rare but possible risks include: Blood clots in the pelvic veins

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

You may benefit from having your prostate cancer treated with a minimally invasive procedure without having to undergo surgery, radiation, or hormone treatment. You will also benefit from being enrolled in a close follow up program to monitor the response to treatment. This way, if cancer recurrence is found at any time, we will be able to either apply the same laser ablation treatment again if you are still a candidate or refer you to another form of traditional treatment.

In addition, your participation may help future patients having this same procedure by establishing the potential benefit of this new treatment method.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

The treatment provided by this study is experimental. If you decide not to enter this study, there is care available to you outside of this research study. You may still choose to be on active surveillance or go to surgery or radiotherapy which are the current standard of care treatment options. The study doctor will discuss these with you. You do not have to be in this study to be treated for prostate cancer.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Medical Record
If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury
If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory has not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Sherif Nour at telephone number (404) 778-3164. You should also let any health care provider who treats you know that you are in a research study.

Costs
Emory Healthcare does not plan to pay for any items or services that you may receive if you take part in this study.

You will have to pay for the items or services that are part of this study. Emory Healthcare will not pay for your regular medical care. If you have insurance, Emory Healthcare will submit claims to your insurance for items and services that are part of this study. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that Emory has not paid.

Precertification will be done to determine if your insurance will cover the procedure. You will be informed and billed for the procedure or any part not covered by insurance if you take part in the study.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study .

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. Sherif Nour is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: sherif.nour@emoryhealthcare.org

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study

was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact the PI, Dr. Sherif Nour at (404) 778-3164:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____ _____

Signature of Legally Authorized Representative with authority for research decisions **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**