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CONSENT FOR CANCER RESEARCH

Project Title: CASE 11813: Magnetic Resonance Guided Focal Stereotactic Body Radiation Therapy for Localized Prostate Cancer
Principal Investigator: Elisha Fredman, MD
Sponsor: Case Comprehensive Cancer Center through an Elekta SBRT Research Grant

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Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at University Hospitals (UH).

1. Introduction

We are asking you to participate in a research study. The purpose of this document is to summarize your discussion with the research team and provide you with written information to help you decide whether you want to participate in research. Your decision is completely voluntary.

Your treating doctor may also be an investigator on this research study. If so, your doctor will have an interest in both your welfare and in the research study. You are not required to take part in this research study offered by your doctor. You may ask for a second opinion from another doctor who is not linked to this study. If you choose not to be in this study, the quality of your regular medical care will not be affected.

Please ask any questions you may have about the study or this consent form before signing it. Please take your time to make your decision. You will be given a copy of this form to keep.

Case Western Reserve University (Case) holds a patent for the technology that is the focus of this research. As such, Case, as well as University Hospitals Cleveland Medical Center (UHCMC), could gain financially from the commercialization of this technology. This represents a conflict of interest for both institutions.

If you have any questions regarding conflicts of interest, please ask your study doctor or call the University Hospitals Institutional Review Board at (216) 844-1529.

2. Purpose

Focal Stereotactic Body Radiation Therapy (SBRT) is an investigational (experimental) form of radiation therapy for patients with prostate cancer. SBRT is delivered by a Food and Drug Administration (FDA) approved radiation therapy delivery device, using doses that are typical for a whole gland treatment. The investigational part of this study is selecting a part of the prostate shown on imaging to harbor cancer for treatment for high or focal radiation therapy that would spare areas of the prostate that are not found to have cancer on imaging studies. Focal image-guided radiation therapy is a new therapy that may be able to help patients experience fewer side effects by targeting only diseased tissue and avoiding healthy areas not shown to have cancer.

To help find the diseased tissue, this study will be using advanced magnetic imaging resonance (MRI's) called "Multiparametric MRI". This is an MRI that can help to detect the difference between tumor tissue with non-tumor tissue. Another investigational part of this study is using the MRI to both guide treatment planning for focal therapy between therapy sessions and following therapy to assess changes in response to treatment. We will also use biopsy data with the MRI scans to identify pathology confirmed MRI scans so that we can better know the location of tumor.

The main goal of this research study is to use multiparametric MRI's to better treat low to intermediate risk prostate cancer. Other purposes of this research study will be to hopefully help lead to less toxicity from focal SBRT and maintain a better quality of life for patients compared to treatment directed to the entire prostate gland.

How Many People Will Take Part In This Study?
About 12 subjects (men who are at least 18 years of age) will take part in this study at University Hospitals Cleveland Medical Center

3. Study Procedures
In this study, you will have a multiparametric MRI to see where to focus your radiation therapy. You will then undergo radiation therapy treatment for 1 week (3 days out of the week will be radiation therapy). When radiation therapy is finished, you will follow up with your physician for up to two years.

Before You Begin This Study:
You will need to have certain exams, tests or procedures (called "screening tests") to help your study doctor determine if you are eligible for this study. This is called the pretreatment "screening" period. You will be asked to sign this consent form before beginning any screening tests. Some of these exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. Some of the tests and procedures need to be done near the date of your first MRI or SBRT treatment. If they were done too long ago they may need to be repeated. Your doctor/study team will discuss which, if any, tests need to be repeated.

Before your first SBRT treatment, you will be asked to visit the clinic to have the following procedures done:

- A review of your medical history
- You will be asked about any medications you might be currently taking. It's important that you let your doctor know about all medications you are taking. This includes medications that are by prescription, over the counter, vitamins/nutritional supplements herbal products, and hormonal therapy.
- You will be asked how well you are able to do your normal activities (this is called

"Performance Status").

- You will be asked to complete questionnaires about your quality of life.
- A physical examination, including vital signs (blood pressure, pulse, and temperature), height, and weight will be recorded.
- Blood samples (about 1 tablespoon) will be taken for routine tests to check your blood counts (numbers of each type of blood cell) and chemistries (to evaluate your overall health status by checking things such as your kidney and liver function).
- Pelvic MRI scans with multi-parametrics (a special type of MRI that takes multiple images of your prostate cancer) and contrast of your tumor(s) will be taken to measure the extent of your disease if one has not been done within the past 180 days.
- Prostate-specific antigen, or PSA, will be taken. PSA is a protein produced by cells of the prostate gland. The PSA test measures the level of PSA in a man's blood.
    - For this test, a blood sample is sent to a laboratory for analysis.
- You will have a bone scan if your study doctor says it is clinically necessary and if one has not been completed in the past 90 days
    - A bone scan is imaging similar to an MRI to look at the health of your bones
- A digital rectal exam if not completed in the past 90 days
    - A digital rectal exam is done to check for problems with organs or other structures in the pelvis and lower belly. During the examination, the doctor gently puts a lubricated, gloved finger of one hand into the rectum. He or she may use the other hand to press on the lower belly or pelvic area.

Screening Biopsy and Fiducial Placement – visit #2 (this visit should take about 2 ½ hours)

- A physical examination, including vital signs (blood pressure, pulse, and temperature), height, and weight will be recorded
- You will be asked about any medications you might be currently taking. It's important that you let your doctor know about all medications you are taking. This includes medications that are by prescription, over the counter, vitamins/nutritional supplements herbal products, and hormonal therapy.
- You will be asked how well you are able to do your normal activities (this is called "Performance Status")
- Some patients may have a hydrogel spacer placed to spare the rectum during radiation treatment as standard of care.
- Fiducial markers (small metal markers about the size of a grain of rice) will be placed within the prostate to guide daily set up during your three SBRT treatments
    - This procedure uses transrectal ultrasound imaging in the outpatient surgery center with sedation to place small markers
    - During this procedure additional biopsy samples may be acquired if you have not had a targeted biopsy prior to fiducial placement just prior to placing the marker. We will use MRI images to guide the biopsy and marker to the area of the prostate that appears to have cancer on imaging. We will also sample other areas of the prostate during this procedure to check the prostate for the presence of

cancer that is not shown on imaging.

- Should additional cancer be found during this investigational biopsy procedure we will advise you and refer you to consultation for evaluation of other treatment options off study, and you will be withdrawn from this study.

During The Study

If the exams, tests, and procedures show that you can be in the study, and you choose to take part, then you will have the following tests and procedures done. These tests and procedures are part of regular cancer care, so you would have them done even if you were not on this study:

On Study MRI and CT scans– visit #3 (This visit should take about 2 hours)

- CT Pelvic CT to help plan your radiation treatment
  - A CT scan uses a computer that takes data from several X-ray images of structures inside your body. This will help the doctors plan your radiation treatment.
- Blood Draw, approximately 2 teaspoons of blood will be drawn to make sure that you can also have an MRI.
- Pelvic MRI

SBRT #1– visit #4 (This visit should take about 1 ½ hours)

- Radiation therapy treatment

SBRT #2– visit #5 (These visits should take about 1 ½ hours)

- Radiation therapy treatment

MRI– visit #6 (This visit should take about 1 hour)

- Pelvic MRI with contrast unless contraindicated

SBRT #3– visit #7 (These visits should take about 1 hour)

- You will be asked about any side effects you may or may not be having (this may be completed by telephone call within 7 days of this visit) Radiation therapy treatment

Your Responsibilities:

During this study, you should call your study doctor immediately if you have any side effects in between your treatment days while on this study. You may also be hospitalized if you have serious side effects.

How long will I be in the study?

You will receive study treatment and follow up until any of the following happen:

- your doctor has determined that your cancer has progressed,
- the study treatment causes symptoms prompting you to stop participating
- the completion or termination of the study.

- severe side effects occur,
- you or your physician wishes to discontinue treatment, or
- the study Sponsor finds it necessary to limit or end this study.

After you are finished with the study treatment, the study doctor will ask you to visit the office for a treatment completion visit described below within 30 days after your last radiation treatment (RT).

End of Study
After you are finished with your RT, the study doctor will ask you to visit the office for follow-up exams for at least 8 visits to determine if any further medical treatment is needed as a result of the study. After this you will continue follow-up with your regular medical team (i.e., your Radiation Oncologist and Urologist and primary care physician) who will evaluate you for further care as appropriate. If your PSA level shows an increase that is suspicious for recurrence, then an MRI directed biopsy could be used as the standard of care to determine treatment options for either a local recurrence or disease progression outside of the prostate gland. A local recurrence within the prostate may be able to be treated with surgery or other local therapy such as further forms of radiation. It may be possible that the risk of complications could increase as a result of additional therapy. Your doctors would help you choose the best option available based on the clinical circumstances involved at that time.

Follow up, every 3 months for up to 24 months – visits #8 - #16

- A physical examination, including vital signs (blood pressure, pulse, and temperature), and weight will be recorded
- You will be asked about any medications you might be currently taking. It's important that you let your doctor know about all medications you are taking. This includes medications that are by prescription, over the counter, vitamins/nutritional supplements herbal products, and hormonal therapy.
- You will be asked how well you are able to do your normal activities
- You will be asked to complete questionnaires about your quality of life
- You will be asked about any side effects you may or may not be having

Post SBRT Follow up Measurements

- Prostate-specific antigen, or PSA, will be taken at ALL follow up visits
- A digital rectal exam to check for problems with organs or other structures in the pelvis and lower belly, will be completed at ALL follow up visits
- Blood Draws will be done at 6, 12, and 24 month follow up visits prior to MRI if not previously drawn in past 42 days
- Pelvic MRI to be completed at 6, 12, and 24 month follow up visits
- Questionnaires about your quality of life will also be completed at 6, 12 and 24 months

You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so that any risks from SBRT or multiparametric MRIs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

4. Risks

High dose radiation can have both short term and long term side effects. As with any experimental procedure, there may be adverse events or side effects that are currently unknown and some of these unknown risks could be permanent, severe, or life-threatening. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you finish treatments. In some cases, side effects can be serious, long lasting, or may never go away. As with any investigational procedure (procedures being done for experimental purposes), there may be adverse events or side effects that are currently unknown.

During your participation in this study, you should not receive any other treatment for your cancer (this includes any chemotherapy, radiation, surgery, or any other agents used to reduce or eliminate your tumors). If your study doctor decides that one of these options would be better for you, you will be withdrawn from the study.

Risks of Stereotactic Body Radiation Therapy (SBRT)

All patients will be seen by their Radiation Oncologist during radiation therapy. Any observations regarding radiation reactions will be recorded and should include attention to the following potential side effects:

- Small bowel or rectal irritation which includes symptoms like;
    - stomach muscle cramping
    - diarrhea
    - rectal urgency, the feeling like you need to defecate suddenly and intensely
    - swelling of the muscles and lining of the rectum
    - passage of bright red, bloody stools
- Bladder complications such as;
    - urinary frequency/urgency
    - very painful urination
    - blood in the urine
    - urinary tract infection, also called a bladder infection, which can lead to painful urination
    - incontinence which is involuntary urination or bowel movements
- Radiation dermatitis, which is swelling and redness of the area receiving the radiation therapy.

Potential Risk or Discomfort from Procedures
You may have a number of CT scans, nuclear scans, and MRI scans that are part of the regular care for this condition, whether or not you participate in this research. These imaging procedures will not add to the risk of the research. However, concerns about the overall radiation exposure or MRI safety issues should be discussed with a study doctor.

Prostate Biopsy Procedure
Risks associated with biopsies include pain, redness, swelling, low blood pressure, excessive bleeding, bruising, or draining at the needle site, abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site. 2-3% of patients require hospitalization after a tumor biopsy.

Blood Draws
The insertion of the needle to draw blood is painful; however, the discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

CT Scans
A liquid solution known as a contrast is frequently used in CT scans. The contrast is a solution used to make certain organs, blood vessels and tissues "stand out" to better image your disease. It is possible that you may develop an allergic response to the contrast agent. You may experience nausea, flushing, warmth and a salty taste. The dye can also cause water loss or damage to the kidneys, which may lead to kidney failure. This is a concern if you have poor kidney function, dehydration, or diabetes, especially if you take Metformin® (Glucophage) to control your diabetes. You will be asked not to move during the test, but relax and breathe normally. You might be uncomfortable while you are in the tunnel-shaped machine. Some patients have felt claustrophobic, or afraid of the enclosed space, during this test.
There is also a slight risk of developing an allergic reaction to the iodine contrast material. The reaction can be mild (itching, rash) or severe (difficulty breathing or sudden shock). Death resulting from an allergic reaction is rare. Most reactions can be controlled using drugs. Be sure to tell your doctor if you have allergies of any kind (such as hay fever, iodine allergy, eczema, hives, or food allergies).

You will be exposed to a limited and medically acceptable dose of radiation during the procedure. There is always a slight risk of cell damage from being exposed to any radiation, including the low levels of X-rays used for a CT scan. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. The CT scans done for this study will give your body the equivalent of about 3 extra years' worth of this natural radiation. If you are concerned with radiation exposure, please discuss this with your doctor.

Magnetic Resonance Imaging (MRI)
An MRI uses magnetic energy and radio waves rather than x-ray radiation. A small amount of

patients may experience claustrophobia, or an inability to be in a confined space without being given a sedative (a drug used to calm them). In addition, you will hear loud, knocking noises. Occasionally, subjects will report a mild headache from the "knocking" sound. Temporary hearing loss has been reported from this loud noise. You will be asked to wear ear plugs. At certain times during the MRI, you may be asked not to swallow for a while, which can be uncomfortable.

Watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any metal implants within the body you will not be able to undergo an MRI since metal implants interfere with the MRI system's magnetic field. You will still be able to participate in this study, but would have a CT scan instead of an MRI. Before you have the MRI scan, make sure to tell the operator/investigator if you have any of the following:

- a cardiac pacemaker or any other biomedical device in or on your body,
- any metal objects (especially surgical clips), devices, or implants that are in or on your body. In some cases, having those devices means you should not have an MRI scan performed.
- if you have metal-containing pigment in tattoo dye or permanent makeup. There have been reports of people with tattoos or permanent makeup who experienced swelling or burning in the affected areas. This seems to occur only rarely and apparently without lasting effects.
- any history of head or eye injury involving metal fragments,
- if you have ever worked in a metal shop,
- if you are claustrophobic (the fear of being in a narrow or enclosed space).
- if you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies. Subjects with severe kidney disease sometimes have a bad reaction to gadolinium contrast. The condition is called nephrogenic sclerosing fibrosis (NSF). It can cause skin to tighten or scar and can damage internal organs. Sometimes it can be life-threatening. There are no reports of NSF in subjects with normal kidney function. Before you have a MRI or CT scan requiring an injection of gadolinium contrast, you will have a blood test in order to check the function of your kidneys. Based on your medical history and the results of the test, a doctor will decide whether it is safe for you to undergo the MRI or CT scans with a contrast agent.

We will use MRI contrast agent that is approved by the FDA and commercially available. There is a risk of an allergic or fibrotic reaction, which occurs more often with iodine based contrast (for CT) than with MRI contrast agents. Every effort will be made to minimize the risk of such reactions in this study. Generally, an injection of contrast agent will be used. As with all such injections, bleeding, bruising, dizziness, fainting or infection may occur. Also, the injection may be painful but the discomfort should be brief and efforts will be made to minimize the pain.

The MRI scanner makes a loud buzzing sound during the exam that could affect your hearing. In order to protect you from this sound, you will be provided earplugs during the exam. There might also be some claustrophobia-related discomfort involved with being required to lie still in a small space. If this occurs, you can signal the technologist attending the MRI who will stop imaging.

Bone Scan

A bone scan is a test that helps diagnose and track bone disease. A bone scan will be done when you first start the study. For a bone scan, you will receive an injection of a tracer into a vein in your arm. You will need to lie still on a table while a machine with an arm-like device supporting the camera passes over your body to record the pattern of the tracer being absorbed by your bones. This is painless. A scan of your entire skeleton will take up to 60 minutes. You may find the injection and the need to lie still during the scanning procedure mildly uncomfortable. The risk of an allergic reaction to the tracer is extremely rare. We are all exposed to radiation on a daily basis both from natural (sun and earth) and man-made sources that we call background radiation.

Reproductive Risks

We also advise that your female sexual partner not become pregnant while involved in this study.

Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you choose to be sexually active, you should use an appropriate “double barrier” method of birth control: female use of a diaphragm, intrauterine device (IUD), contraceptive sponge, prescribed “birth control” pills, injections, or implants, in addition to male use of a condom. You should use contraceptives during treatment, and for six months after you stop treatment. If you choose to be sexually active during this study, you understand that even with the use of these birth control measures pregnancy could still result. Should your sexual partner become pregnant during the course of therapy you are requested to notify one of the study doctors.

5. Benefits

There is no guarantee that you will receive any benefits from this study, and taking part in this study may or may not cause your health to improve. Information from this study may help doctors learn more about SBRT and multiparametric MRI’s. This information may benefit other patients with cancer in the future.

6. Alternatives to Participation

If you do not wish to take part in this research study, your study doctor will discuss alternate treatment options with you, including their benefits and risks. These may include:

- Getting treatment or care for your cancer without being in a study.
- Taking part in other investigational studies with if they are available.

Talk to your study doctor about each of these choices before you decide if you will take part in this study. If you decide not to participate, withdraw your participation after starting the study, or are taken off the study, your study doctor will discuss all other treatment options with you.

7. Costs and Compensation

Your involvement in this research study is voluntary and you will not be paid for your participation.

The fiducial marker placement procedure is part of your standard of care for SBRT treatment. The multiparametric MRI's taken in between treatment days for SBRT and following therapy at 6, 12 and 24 months to monitor for disease progression will be provided free of charge by an Elekta SBRT Research Grant Program while you are participating in this study. Neither you nor your insurance provider will be responsible for the costs of any research-only tests.

Philips Medical Systems is providing FDA approved equipment that will be used during the screening biopsy to use the MRI and ultrasound data to guide the biopsy and track the location of the biopsy site where tissue was taken. You and/or your health plan/insurance company will be responsible for the additional cost of the screening biopsies acquired during this procedure. You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study (i.e., medical history, review of medications, physical exams, performance status, routine blood tests, biopsy related pathology cost, x-rays and/or scans for tumor measurement, and therapeutic radiotherapy). Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://www.cancer.gov/clinicaltrials/learningabout.

Notice for Managed Care (Medicare Advantage Plan) Beneficiaries

Certain services that are required for your care as a participant in a clinical trial can be billed to, and paid by, your medical insurance. These services are referred to as "covered" clinical trial services. However, if you have a Medicare Advantage Plan as part of your medical insurance, this insurance cannot be billed for covered clinical trial services. Instead, traditional Medicare will be billed, and will pay for those services. This has an impact to you. When traditional Medicare pays for such services, you will be responsible for paying the coinsurance amounts applicable to these services, in addition to any other deductibles or co-insurance you may have on your other health coverage. Please speak with a financial counselor to understand what the specific financial impact will be for you associated with participating in this clinical trial.

8. Research-Related Injury
If you believe that you are injured as a result of the research procedures being performed, please immediately contact the study doctor.

If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals; however, University Hospitals has no plans to provide free care or compensation for lost wages. You or your insurance company will be charged for treatment of research-related injuries.

Further information about research-related injuries is available by contacting the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979.

9. Privacy and Confidentiality
Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Elisha Fredman, MD, and the research study staff at University Hospitals for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the, University Hospitals Institutional Review board and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- Case Comprehensive Cancer Center, its study monitors and representatives
- Elekta SBRT Research Grant Program
- Philips Medical Systems
- Innovation Center Grant Funding Program
- The Food and Drug Administration;
- The Department of Health and Human Services;
- The National Cancer Institute (NCI);
- Other Institutional Review Boards;

- Data Safety and Monitoring Boards;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Elisha Fredman, MD
Case Comprehensive Cancer Center
University Hospitals Cleveland Medical Center
11100 Euclid Ave.
Cleveland, OH 44106

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside University Hospitals cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

University Hospitals will not use your information collected in this study for another research purpose without your written permission; unless the University Hospitals Institutional Review Board assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

10. Voluntary Participation

Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

11. Questions about the Research
If you have any questions, you can ask the Principal Investigator and/or research staff at (216) (216)286-3903.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study, research participant's rights; research-related injury; or other human subjects issues, you may contact the University Hospitals Cleveland Medical Center's Research Subjects Rights Phone line at 216-983-4979.

Emergency Contact Information
If you are a University Hospitals patient, and you need to contact study staff outside normal business hours, you may contact 216-844-3951 and you will be transferred to the answering service, which can put you in contact with Dr. Fredman, or the oncologist (cancer doctor) on call.

Where Can I Get More Information?
You may call the National Cancer Institute's Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237)
You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

US National Institutes of Health (NIH) Clinical Trial Database:
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.

12. Signature
Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

_____	_____	_____
Signature of Participant	Date	Printed Name of Participant

CONSENT FOR CANCER RESEARCH

Project Title: CASE 11813: Magnetic Resonance Guided Focal Stereotactic Body Radiation Therapy for Localized Prostate Cancer
Principal Investigator: Elisha Fredman, MD
Sponsor: Case Comprehensive Cancer Center through an Elekta SBRT Research Grant

[USE THE SIGNATURE BLOCK BELOW WHEN A WITNESS IS USED IN THE CONSENTING PROCESS (Common examples include: Inclusion of illiterate individuals, blind individuals, or individuals who are physically unable to provide informed consent.)]

_____	_____	_____
Signature of Witness	Date	Printed Name of Witness

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

_____
Printed Name of Person Obtaining Consent