CONSENT FOR CANCER RESEARCH

Project Title: CASE 10814 Pilot Study Evaluating the Role of Histopathology Correlation in Treatment Planning
Principal Investigator: Bryan Traughber, MD
Sponsor: CASE CCC

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**.**

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. Your decision is completely voluntary.

Your 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.

One or more of the Investigators conducting this study serve as consultants for Philips, the company that makes the Uronav system, which is a device that is being used in this study. These financial interests are within permissible limits established by the Case Western Reserve University Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask you study doctor or call the University Hospitals Institutional Review Board at (216) 844-1529.

2. Purpose

You are being asked to take part in a clinical research study because you have been diagnosed with low to moderate risk prostate cancer, and you will be having Brachytherapy treatment.

The main purpose of this study is to test similarities and differences of biopsy tissue structures and the findings from the intraprostatic MRI (internally guided MRI).

As part of standard MRI guided biopsy procedure, virtual markers are placed on the image for the MRI and or ultrasound to help plan the procedure. These markers are called fiducial markers. As part of this research study, the Uronav device will be used to help position those markers and track the biopsy location in your prostate before your routine prostate brachytherapy. This will be used to evaluate the dose of radiation to the positive biopsy locations in addition to the whole prostate gland.

The Uronav device has been determined by Food and Drug Administration (FDA) to be similar enough to other devices that are already FDA approved for use in patients with prostate cancer, so it is not considered investigational. Your radiation therapy treatment will be planned by your treating physician and will not be experimental or part of this research study.

This study is also collecting information on the doses of radiation in your brachytherapy, the amount of space in your body it covers, and how close the radiation is to your organs.

About 6 subjects (men who are at least 18 years of age) will take part in this study at University Hospitals.

3. Study Procedures
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. 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.

During the Study:
You will receive standard treatment during your involvement in this study. Your study participation will total 5 visits.

<u>Screening:</u>
- You will be asked to sign this consent form, after you have had time to take it home and read it.
- Your vital signs (blood pressure, pulse, temperature, and respiration) will be recorded
- You will be asked about your medical and cancer history.
- You will be asked what medications you are currently taking. This includes over-the-counter medications, vitamins, herbal supplements, and illegal substances.
- You will be asked about how well you can perform daily tasks.

Biopsy:
You will undergo an Uronav guided biopsy. This procedure is standard but involves a research related device. The tissue from the biopsy will be used to research the main purpose of the study as described on page 1 of this consent form. Your tissue will only be used for this purpose and will not be stored for future testing.
  - All biopsies will be completed per standard of care recommendations.

<u>Visit 3 about 2 weeks after biopsy (this may be a nurse phone call):</u>
- You will be asked about any side effects you may be having. This includes side effects

from the Uronav guided biopsy, which is a research related device.
- You will be asked about how well you can perform daily tasks

Visit 4 (about 30 days after biopsy):
- Your vital signs (blood pressure, pulse, temperature, and respiration) will be recorded
- You will be asked about your medical and cancer history.
- You will be asked what medications you are currently taking. This includes over-the-counter medications, vitamins, herbal supplements, and illegal substances.
- You will be asked about how well you can perform daily tasks.
- You will be asked about any side effects you may be having. This includes side effects from the Uronav guided biopsy, which is a research related device.

Visit 5 (about 3 months after biopsy):
- Your vital signs (blood pressure, pulse, temperature, and respiration) will be recorded
- You will be asked about your medical and cancer history.
- You will be asked what medications you are currently taking. This includes over-the-counter medications, vitamins, herbal supplements, and illegal substances.
- You will be asked about how well you can perform daily tasks.
- You will be asked about any side effects you may be having. This includes side effects from the Uronav guided biopsy, which is a research related device.

How long will I be in the study?
This study involves a one-time research only procedure. You will be on the study until you have completed all 5 study visits listed above.

4. Risks
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 medication to help lessen side effects. Many side effects go away soon after you undergo the Uronav guided biopsy. 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.

Risks of the *Uronav guided biopsy procedure:*
A transperineal biopsy is a biopsy procedure in which a sample of tissue is removed from the prostate for examination under the microscope. The sample is removed with a thin needle that is inserted through the skin between the scrotum and rectum and into the prostate.

The risk for prostate edema (swollen prostate) and urinary obstruction (blocked urine) may be increased due to the extra transperineal needle placement during the biopsy. If this happens, you will be asked to maintain a Foley Catheter overnight to allowed edema to resolve, and to avoid any further obstruction the following day. A Foley catheter is a flexible tube passed through the urethra and into the bladder to drain urine. Your doctor will give you further instructions if this is necessary.

Other expected risks include infection requiring additional antibiotic treatment beyond the standard postoperative antibiotic, and readmission to the hospital for pain.

The Philips Medical's Uronav device poses no significant risk, however, any unanticipated complications or infections will be recorded by study staff.

Potential Risk or Discomfort from Procedures:

Reproductive Risks
Men who are able to father children should use adequate contraception.

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. 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.

If your female sexual partner becomes pregnant while you are taking part in this study, you must notify one of the study doctors so that management of the pregnancy can be discussed.

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 the Uronav system. 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 if they are available.
- Choosing not to participate in this study.

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 Uronav system, will be used in your guided biopsy free of charge, provided by Philips Medical, while you are participating in this study. Neither you nor your insurance provider will be responsible for the costs of any research-only tests or procedures.

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, x-rays and/or scans for tumor measurement). 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 injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

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 Bryan Traughber, 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. Your PHI may also be used by and/or disclosed (released) to:

- Philips Medical, its study monitors and representatives
- 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;
- Case Comprehensive Cancer Center

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:

Bryan Traughber, 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.

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) 286-3903.

Emergency or after-hours 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. Traughber, or the oncologist (cancer doctor) on call.

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.

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

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

_____
Printed Name of Person Obtaining Consent