**Official Title:**

Acoustic Radiation Force Impulse (ARFI) Imaging for Targeted Prostate Biopsy

**NCT:** NCT04607135

**IRB Document Date:** August 18, 2022

DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
**Acoustic Radiation Force Impulse (ARFI) Imaging**
**for Targeted Prostate Biopsy - 2**

**Concise Summary**

The purpose of this study is to evaluate a new ultrasound technique. This technique may provide additional and improved information about the stiffness and sizes of the internal structures of your prostate in order to improve the guidance for a targeted biopsy.

The investigational, custom-designed probe and needle guide will be used to produce images of your prostate and provide guidance for up to 4 additional biopsy samples (cores) prior to a standard magnetic resonance (MR) ultrasound fusion biopsy procedure. Above the time required for the MR ultrasound fusion biopsy, this study will take up to 30 additional minutes of time for collection of the investigational device guided collection of biopsy samples

Risks of participation include increased time under anesthesia (to collect additional biopsies) and slight heating of tissue.

Full study details, risks and potential benefits are outlined below. Please discuss all information with your doctor before deciding to participate.

## INTRODUCTION

You are being asked to take part in this research study because you have been referred for ultrasound guided biopsy with suspicion of prostate cancer, and you have chosen to have a magnetic resonance (MR):ultrasound fusion targeted biopsy. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

This study is being conducted by researchers from the Departments of Surgery (Primary contact: Dr. Thomas Polascik), and Biomedical Engineering (Primary contact: Dr. Kathy Nightingale) at Duke University Medical Center. This study is being supported by grants from the National Institutes of Health. Portions of Dr. Thomas Polascik and his research team's salaries may be paid by these grants.

The technology and method used in this study was developed by investigators at Duke including Dr. Nightingale and Dr. Mark Palmeri. Patents related to this technology have been licensed by Duke to other companies (including Siemens and Samsung), and in some cases Duke and the investigators have received royalty payments. If the technology is commercially successful in the future, the developers and Duke University may continue to benefit financially.

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## WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Thomas Polascik will be your doctor for the study (study doctor) and may be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate a new, specially-designed ultrasound probe. This is a tool that can provide information about the stiffness and sizes of the internal structures of your prostate. The goal is to provide doctors with a better way to visualize prostate cancer, which would help guide prostate needle biopsy toward regions that appear to be cancer and potentially increase the procedure's diagnostic accuracy. If effective, future prostate needle biopsy procedures may provide more accurate diagnoses of prostate cancer for patients, without needing to perform a separate MR imaging study.

The ultrasonic method used in this study is investigational. The word "investigational" means the study device is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA). Additionally, although many ultrasound devices are commercially available, the probe and biopsy needle guide used in this study are not approved by the FDA for clinical use, so they are considered investigational. The probe and biopsy needle guide are prototypes that were designed by our research team in collaboration with Siemens, a manufacturer of ultrasound machines and probes. They are designed specifically for prostate stiffness imaging and biopsy. The probe has been tested by Siemens for safety and biopsy targeting accuracy.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 60 people will take part in this study at Duke.

## WHAT IS INVOLVED IN THE STUDY?

If you decide to participate in this study, Dr. Polascik will perform a standard targeted ultrasound prostate biopsy. This is a procedure where samples of tissue (cores) and images are taken of your prostate. He will use the investigational ultrasound probe and needle guide to perform the procedure.

During a standard ultrasound imaging session, ultrasound sound waves are sent into the tissue and bounce off of structures to make an image that appears on a screen. For the new method, sound waves are sent in a series and are expected to "push on" the prostate and move it a very small amount (the width of a hair). The stiffer the structure (prostate), the less it will move. This motion will be detected by the ultrasound system. In this research study, the new kind of images are able to be taken with the same system that is used for the standard imaging. You will have both standard ultrasound imaging as well as investigational ultrasound imaging done during your procedure.

The study doctor will perform a standard MR-ultrasound fusion biopsy procedure following the current standard of care procedures.

And, from the additional pictures that are taken with the investigational device, the study doctor will identify the most cancer-suspicious targets and perform up to 4 additional biopsies from up to 3 of those suspicious areas.

The results of your biopsy will be reported to you and used by the study doctor to plan care for your condition. If you choose not to participate in this study and do not sign this consent form, you will continue to receive care, but not as a part of this study.

**HOW LONG WILL I BE IN THIS STUDY?**
Participation in this study lasts for the length of time of your procedure. In addition to the standard time needed to perform an MR:ultrasound fusion targeted prostate biopsy, this study will lengthen your procedure time by approximately 30 minutes. The added time is required to take the additional images and biopsy samples.

You can choose to stop participating at any time during the study without penalty or loss of any benefits to which you are entitled.

**WHAT ARE THE RISKS OF THE STUDY?**
The method uses high-energy ultrasound to "push on" tissue for very short times. If the high-energy ultrasound is applied for long times, or if higher energy levels are used, it can cause tissue damage (bruising and heating of the tissue). The method is designed to use short times to prevent tissue damage.

For the ultrasound energy levels that are used, some slight tissue heating will occur. Heating during the investigational ultrasound is similar to the heating in routine therapeutic ultrasound treatments. Therapeutic ultrasound is often used in physical therapy to generate heat in sore muscles and joints in order to promote healing (like putting a heating pad inside the body).

The risk of injury from the investigational device and method is the same to that normally encountered in any diagnostic or therapeutic examination using ultrasound including a standard of care ultrasound guided biopsy procedure. These risks could include infection, bleeding, urinary retention, worsening of hemorrhoids, a rectal tear (exceedingly rare), and pain and discomfort.

Risks also include the increased time required for the procedure, which will lengthen the time of anesthesia. Procedure time could be increased as much as an additional 40 minutes. This procedure may be done as an outpatient procedure in the clinic or as an inpatient procedure in the hospital. Local anesthesia, general anesthesia, or conscious sedation may be used. You and your doctor will discuss the best course of action.

Risks of biopsies including the additional biopsies for this study include infection, bleeding, urinary retention, irritation of hemorrhoids, rectal tear, pain, and discomfort.

There may be risks, discomforts or side effects that are not yet known.

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**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
The images generated with this technology may improve diagnostic imaging of your suspected cancer. Imaging may improve targeted biopsy collection by the study doctor which may also improve accuracy of your diagnosis. These benefits cannot be guaranteed. We hope that in the future the information learned from this study will benefit other patients who require prostate biopsy.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, Dr. Polascik and his study team will analyze the results of your study ultrasounds and any other available images of your prostate, biopsy results, and any prostate health relevant data available in your medical record. The results will not be reported to an outside agency except your treating physician.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the National Institutes of Health (NIH) and the Duke University Health System Institutional Review Board. If any group reviews your research record, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Results from this study may be used for scientific publication. These results might include ultrasound pictures of your prostate, ultrasound elasticity measurements from your prostate, and results from other clinical measures and imaging studies related to your prostate health. While the information in the data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**WHAT ARE THE COSTS?**
There are no additional costs to you to participate in this study. You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study.

**WHAT ABOUT COMPENSATION?**
There is no compensation available for your participation in this study.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

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For questions about the study or research-related injury, contact Dr. Polascik at 919-684-4946 during regular business hours. After hours and on weekends and holidays please call 919-684-8111 and ask the Duke Operator to page Dr. Polascik for you.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Thomas Polascik in writing and let him know that you are withdrawing from the study. The mailing address is 2804 DUMC, Duke University Medical Center, Durham, NC 27710.

Your study-related data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, or if you have problems, concerns, or suggestions about the research, contact Dr. Thomas Polascik at (919) 684-4946.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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**STATEMENT OF CONSENT**

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

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| _____ | _____ | _____ |
| Signature of Subject | Date | Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |
| _____ | _____ | _____ |
| Signature of Witness (if applicable) | Date | Time |

_____
Printed name of Witness