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Are you participating in any other research studies? _____ Yes _____No

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Protocol Director Name, Geoffrey Sonn, MD at (650) 725-5544. You should also contact him at any time if you feel you have been hurt by being a part of this study.

DESCRIPTION: You are invited to participate in a research study on the use a clinical micro-ultrasound device ExactVu, to systematically image the prostate before biopsy or surgery. The ExactVu device is FDA approved for micro-ultrasound imaging of the prostate. The study will involve use of investigational software that is not FDA approved. The images from the ultrasound system will be saved and compared to other imaging modalities and pathology in order to develop better tools. We hope to reveal ultrasound imaging biomarkers that correlate with prostate cancer, as compared to gold standard pathology or other imaging findings. You have been identified as a candidate for this investigation because you are undergoing either a prostate biopsy or radical prostatectomy for prostate cancer.

This research study is looking for 100 participants and is only being conducted at Stanford.

Procedure Overview:

If you choose to participate, immediately before your prostatectomy or your biopsy the Protocol Director and his clinical research staff will use the ExactVu device and transducer (probe) to make a number of ultrasound images of your prostate. The transducer is about the size of a finger. It is gently placed into your rectum, where it sends out sound waves that allow the study doctor to see your prostate. The images of your prostate will be saved and compared to other imaging modalities and pathology in order to develop better tools for prostate cancer detection using micro-ultrasound.

RISKS AND BENEFITS: The risks associated with the micro-ultrasound imaging are minimal to none and we do not anticipate that participating in this study will harm you**.**

Your participation in this study will allow the researchers to create a database of micro-ultrasound data to develop ultrasound biomarkers for prostate cancer, which may result in potential benefits to future patients with prostate cancer.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

TIME INVOLVEMENT: Your active participation in this study will take approximately 30 minutes to discuss the consent; some time on your own to review the consent and form questions (this can be done at your home); and, when you return to Stanford for your visit, your questions will be answered and you will be asked to consent to the study. The Exactvu device will take approximately 2 minutes to acquire the images.

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If successful, some future patients may be able to avoid a prostate biopsy if the micro ultrasound imaging is normal. In men who do undergo biopsy under micro ultrasound guidance, the targeting could be more accurate so that fewer cancers are missed.

PAYMENTS/REIMBURSEMENTS: PAYMENTS: You will not be paid for your participation. There is no cost to for participating in this study.

PARTICIPANT RESPONSIBILITIES:
As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

CLINICALTRIALS.GOV:

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.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this study is to use a clinical micro-ultrasound to systematically image the prostate before biopsy or surgery. The images from the ultrasound system will be saved and compared to other imaging modalities and pathology in order to develop better tools. We hope to create a database of micro-ultrasound data that will allow us to develop ultrasound biomarkers for prostate cancer.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:
Geoffrey Sonn, M.D.
Center for Academic Medicine
453 Quarry Road
Urology 5656
Palo Alto, CA 94304

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What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to medical record number, demographic data, including age, gender, sex, as well as diagnosis, biopsy specimens, lab tests, surgery information, specific physical examination measures, specific x-rays or MRI imaging information, including any reports such as radiology or pathology reports and previous or current treatments and outcomes. The data will contain information such as your name, address and outside physician contact information.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Geoffrey Sonn, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Exact Imaging
- The Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on October 01, 2116 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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WITHDRAWAL FROM STUDY

The Protocol Director may also withdraw you from the without your consent for one or more of the following reasons.

- The Protocol Director decides that continuing your participation could be harmful to you.
- Failure to follow the instructions of the Protocol Director and study staff.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Geoffrey Sonn, (650) 725-5544. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact the Clinical Research Coordinator Ned Realiza at (650) 498-8496.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and

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- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

COMPENSATION for Research-Related Injury:
All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

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The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*