



RESEARCH CONSENT FORM

Title of Study: Transrectal Photoacoustic Imaging of the Prostate

Principal Investigator: VAMC: VA Palo Alto HCS

What is this research about?

The goal of this research study is to develop better imaging technology for prostate cancer screening and diagnosis. We have developed a dual modality ultrasound and photoacoustic device. While ultrasound imaging provides anatomical features of the prostate, photoacoustic imaging can provide functional and molecular information of the tissue. The proposed dual modality approach may increase the diagnostic accuracy of prostate cancer imaging. Previously, we have validated the device using prostate phantom models. In this study, we would like to test the technology on human prostate tissue which will help us to understand photoacoustic signatures of prostate tissue and compare it to ultrasound and MRI images of the specimen. Ultimately, this may benefit men in the future if our technology proves to be useful as a molecular imaging tool for the early diagnosis of prostate cancer.

What is expected of me? (Procedures)

Patients who are undergoing radical prostatectomy (open or robotic-assisted) are recruited as research subjects. Nothing is expected of the research subject except the agreement to volunteer in the research study and sign the consent document. Intact unfixed prostate specimens taken from radical prostatectomy will be brought to Stanford for the research study and returned to the Pathology Service at VAPAHCS.

The prostate tissue that will be sent to Stanford will not contain patient identifiers ('de-identified'). The prostate tissue will be used to test the efficacy of dual modality ultrasound and photoacoustic device and will also be imaged with our MRI. This test will take about two to four hours. Afterwards, the tissue will be returned to the VA hospital for routine processing by the Pathology Service. We will compare the results from the pathology analysis with our imaging findings. We plan to study 60 such de-identified prostate tissues.

What are the possible risks or discomforts?

No risk.

Will I benefit from the study?

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

What are my alternatives to being in this study?

The alternative is to NOT participate in this study.

Will I get paid?

**RESEARCH CONSENT FORM**

Title of Study: Transrectal Photoacoustic Imaging of the Prostate

Principal Investigator: VAMC: VA Palo Alto HCS

There is NO payment for participating in this study.

Will I have to pay anything?

There will be no costs to you for any of the treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

Do I have to be in this study?

Participation is voluntary and your decision not to participate will not result in any penalty or loss of benefits the participant may be entitled.

Can I change my mind later and stop being in this study?

Participant can withdraw from the study at any time without penalty or loss of benefits.

Will my information be protected from the public?

Your name and your identifying personal health information will remain confidential. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other institutional agencies (VA Research and Development Committee, Stanford Institutional Review Board) and federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

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 principal investigator, is the Chief of Urology at VA Palo Alto Health Care System. He or his research assistant can be reached at. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at or toll free at. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.



RESEARCH CONSENT FORM

IRB USE ONLY

Approval Date: July 31, 2017

Expiration Date: July 31, 2018

Title of Study: Transrectal Photoacoustic Imaging of the Prostate

Principal Investigator: VAMC: VA Palo Alto HCS

Signature of Participant

Date

Print Name of Participant

Person Obtaining Consent:

Signature of Person Obtaining Consent

Date

Print Name of Person Obtaining Consent