UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THE STUDY

Study title: Architectural Heterogeneity in Prostate Cancer using a Fine Needle Photoacoustic Probe

Company or agency sponsoring the study: National Institute of Health, National Cancer Institute

Principal Investigator: Guan Xu, Ph.D., Assistant Professor, Department of Ophthalmology and Visual Sciences, Department of Biomedical Engineering

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Current prostate biopsies remove prostate tissue to be tested for prostate cancer. Tissue removal is frequently accompanied with pain and complications. We're doing a study to validate a fine needle probe called needle photoacoustic probe for the diagnosis of prostate cancer. The needle photoacoustic probe has the same dimensions as a standard biopsy needle. The needle probe integrates two optical fibers and a steel needle sheath. When inserted into tissue, the probe can detect prostate cancer without removing the tissue as current biopsy procedures do.

To achieve the study goal, we will understand the reliabilities of the measurements using the needle photoacoustic probe system.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Participants of this study should:

1) have planned prostate biopsy as part of routine clinical care;
2) are ≥ 40 and ≤ 80 years old.

Subjects meeting the following criteria will be excluded from this study:

1) Known history of bleeding disorders;
2) Subjects taking anticoagulants, no matter doses or washout time;
3) Known allergy to silicone material;

4) Unable to provide informed consent;
5) Either the surgeon or the subject do not think the subject will not be able to complete all parts of the study, the subject will be excluded;
6) Involved in other investigational studies.

3.2 How many people are expected to take part in this study?

We expect to recruit 20 subjects in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The study team will explain the research study and answer any questions you have about the study. If you still want to participate in the study, the study team will request you sign the consent form prior to any activities occurring that pertain to the study. Once your consent is obtained, the study team will look through your medical chart, ask you questions, and begin scheduling tests and procedures to determine if you are eligible for the study. The study team will inform you of the types of tests and procedures required before the study begins.

Once it is determined you are eligible to enter the study, tests and procedures done at your study visits as part of your regular cancer care will continue.

Some tests and procedures may be done that are not part of your regular cancer care and are being done only for this research study. Tests and procedures that are performed more often or are not part of your standard cancer care will be identified below as "Research".

This study will be performed during a prostate biopsy procedure. The standard procedure of prostate biopsy is briefly described here. The subject will be positioned as usual for a biopsy. Anesthesia will be administered as usual clinical care to minimize pain and movement during the procedure. A transrectal ultrasound probe will be inserted. The ultrasound probe will capture the 3D contour of the prostate. If available, the magnetic resonance imaging (MRI) images taken before the biopsy procedure will indicate the suspicious cancer regions in the prostate.

The needle photoacoustic probe will be inserted into the prostate. As mentioned above, the needle probe integrates two optical fibers and a steel needle sheath. The needle photoacoustic probe has the same dimension as a standard biopsy needle, but will not remove any tissue. Instead, the needle photoacoustic probe emits light and receives ultrasound signals generated by the light. The research measurements by the needle photoacoustic probe will be taken at 2 locations guided by ultrasound imaging. Measurements at each location will be less than a minute. The photoacoustic measurements, including the needle insertions and extractions, will take 15 minutes in total at the most.

After the research measurements by the needle photoacoustic probe, standard prostate procedures will continue.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?

As mentioned in the previous section, the measurement will take less than 15 minutes in addition to the standard biopsy procedures.

4.3 When will my participation in the study be over?

We will compare the needle photoacoustic probe measurements with the standard diagnosis by biopsy results. The study ends when the biopsy results are available. We will not provide with you the information on needle photoacoustic probe measurements.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information will be shared with the National Institute of Health.

Your collected information may also be shared with other researchers, both here or around the world, or with companies. Any sharing is subject to contractual obligations with the Sponsor. Additionally:

- With appropriate permissions, your identifiable collected information may be shared, and/or,
- Without your additional consent, your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:
• pain
• infection
• hematuria
• hematospermia
• urinary retention
• hematochezia
• bleeding at the biopsy site
• exposure to low energy laser light source
• photosensitivity reaction
All risks are expected with a standard clinical biopsy procedure, except the exposure to low energy laser light source.

These risks will be minimized by:

We will minimize the risks by monitoring you carefully. We will provide the usual supportive care that would be routinely given to someone with your condition.

The needle photoacoustic probes are repeatedly tested by third party testing institutes for safety and sterilization.

For the risks that are also expected with a standard clinical biopsy procedure, we will use the same methods to minimize the risks, i.e. sanitizing the needle photoacoustic probes before insertion.

For the exposure to low energy laser light source, the light source is fully enclosed. The output light will only be coupled to the needle photoacoustic probe. The subject will be provided with optical protection goggles rated at OD5+ for optical wavelengths used.

Additionally, there may be a risk of loss to confidentiality or privacy. For example, if your identity as a participant in this research or your identifiable health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. The researchers believe that the risks of such improper disclosure are very small because strict privacy and confidentiality procedures for this research have been adopted. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study.

Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors or any other provider or hospital you visit**.**

If you think you have an injury or illness that is related to your participation in this study, it is important that you tell your study doctor immediately. If you have an injury or accident related to this study, the study staff will make sure that you get medical treatment.

You must inform your study doctor immediately if there are any changes in your health/condition, or if you have any concerns regarding the study. If for any reason you are seen by another healthcare provider or admitted to another hospital, you should make known your participation in this research study. These healthcare providers may wish to contact your study doctor to discuss your condition. Your study doctor may need to contact your other doctors if you develop any potentially significant, unexpected diseases or conditions that may have been caused by the study intervention or procedures or are discovered during the study.

The study doctors will monitor the potential risks during your regular biopsy follow-up visits. If complications or adverse effects are detected, treatments will be provided.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any direct personal benefits from being in this study.
Others may benefit from the knowledge gained from this study.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

This is a non-therapeutic studies, in which there is no "alternative" or standard treatment. Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

You are free to partially or completely end your participation in the study. Examples of partially ending your participation would be to refuse to have the needle photoacoustic probe measurements or refuse the access to your biopsy results.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information, this will be reported to the sponsor in order to comply with legal or regulatory requirements.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No. This study only involves a measurement procedure that is done in one session.. Tell the study doctor if you are thinking about stopping or decide to stop. It is important to tell the study doctor if you are thinking about stopping so any risks can be evaluated by your doctor. The study doctor will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell your study doctor or one of the researchers listed in Section 10 "Contact Information" (below).

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7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researchers or your study doctor believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive $100 for completing the study. The completion of this study is defined as the time when the comparison between the measurements taken by the needle photoacoustic probe and the biopsy results are finished.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

The University of Michigan is receiving payments from the National Health Institute to support the activities that are required to conduct the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my privacy?
Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code: a subject ID number, and initials
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

A study number will be assigned to each subject and only the principal investigator and co-investigators will have access to the data collected. The identifying link of PHI to collected research information will be kept in a password protected database that will be accessible only to the Principal Investigator and the co-investigator, thus protecting the identifiers from improper use and disclosure. All forms in which subject data is recorded will be kept in a locked cabinet, which only the investigators will have access to.

All research records will be destroyed after the study has been completed and all papers have been authored. Computer files will be deleted and hard copy materials will be discarded in accordance with UMHS policy.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. We may also share your information with other researchers.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.
- More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc/what-is.htm

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Any records relating to condition, the treatment received and response to the treatment
- Demographic information
- Personal identifiers

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Any records relating to condition, the treatment received and response to the treatment
Demographic information
Personal identifiers

What is here should match the selections in 25-1.1 of the IRB application in eResearch

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results.

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly

  - Learn more about side effects
  - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.

- The researchers may need to use the information to create a databank of information about your condition or its treatment.

- Information about your study participation may be included in your regular Michigan Medicine medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission does not expire, unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION
10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Guan Xu, Ph.D., Assistant Professor, Department of Ophthalmology and Visual Sciences, Department of Biomedical Engineering
Mailing Address: KEC 437, 1000 Wall St, Ann Arbor, MI 48105
Telephone:734 763 3457

You may also express a question or concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

Where can I get more information?
You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent document.

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the signed and dated copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____