



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Pilot study to evaluate the feasibility of measuring (a) intratumoral pressures using a novel piezo- resistive semiconductor catheter and (b) intratumoral stiffness using shear wave elastography with ultrasound
2014-0038

Study Chair: Steven Y. Huang

Participant's Name _____ Medical Record Number _____

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goals of this clinical research study are to learn if using a commercially available device called Millar Mikro-tip catheter can be used to measure the pressure inside a tumor and to learn if stiffness inside the tumor can be measured with shear wave elastography. Researchers want to find out if this pressure and stiffness are related to intratumoral fibrosis (the thickening and scarring of connective tissue).

Shear wave elastography is similar to an ultrasound and uses sound waves to vibrate the tissue in order to study tissue stiffness.

This is an investigational study. The Millar Mikro-tip catheter is FDA approved for measuring blood pressure. Its use in measuring tumor pressure is investigational.

Future patients may benefit from what is learned in this study. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a list of potential side effects below in the Possible Risks section of this consent.

Your participation in this study will be over after we have followed up with you about 30 days after your procedures are completed.

The tumor pressure measurement will be performed at no cost to you. The biopsy is part of the clinical research study on which were initially enrolled. If you have questions regarding the biopsy, please contact your clinical research study doctor.

You may choose not to take part in this study. You may choose to have your routine biopsy without being a part of this study. The study doctor will discuss with you the possible risks and benefits of this option. There is no penalty to you to not take part in this study.

1. STUDY DETAILS

If you agree to take part in this study, during a regularly scheduled ultrasound-guided tumor biopsy that you will have either before or after you begin receiving treatment, the Millar Mikro-tip catheter will be used to take pressure measurements of the tumor and shear wave elastography will be used to take stiffness measurements of the tumor. The 2 measurements will be taken once before the biopsy and once after the biopsy is collected.

To collect a tumor biopsy, a small amount of tissue is removed with a large needle. First you will have a routine scan to identify the location of the tumor for the biopsy. The biopsy needle will be inserted into the tumor to begin the biopsy procedure. With the needle in position, stiffness measurements of the tumor will be performed with shear wave elastography. Shear wave elastography is performed similarly to an ultrasound. A transducer is placed on the skin in the area of the tumor and images of the tumor are sent to a computer. The shear wave elastography procedure should take about 2 minutes.

After the shear wave elastography procedure, the tip of the Millar Mikro-tip catheter will be placed into the tumor through the needle that is already in place for your biopsy. The Millar Mikro-tip catheter will then be used to measure the pressure of the tumor before the biopsy sample is taken. Your regularly scheduled biopsy sample will then be removed with a core needle that has a cutting edge.

After the regularly scheduled biopsy, one additional tumor sample will be collected to test for fibrosis. Then the Millar Mikro-tip measurement and the shear wave elastography procedure will be performed again to take additional stiffness and

pressure measurements of the tumor. In total, this should only take an extra 5 minutes and will not affect the biopsy procedure.

Length of Study

If you are removed from the clinical research study on which you are having the biopsies, you will also be removed from this study.

Up to 25 patients will be enrolled on this study. All will be enrolled at MD Anderson.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. You should discuss these with the study doctor. Many side effects go away shortly after the procedure is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to this study.

The Millar Mikro-tip Catheter may cause bleeding or infection at the puncture site.

Having a **catheter** inserted may cause pain, redness, swelling, bruising, infection, and/or vein irritation may occur where the catheter enters the body. There is also the possibility of the catheter breaking due to shearing.

The risks associated with **ultrasound shear wave elastography** are similar to having an ultrasound and are considered to be minimal.

Having **tumor biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Females: Taking part in this study can result in risks to an unborn baby, so you should not become pregnant while on this study. If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away. Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Steven Y. Huang, at 713-794-1152) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data

from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if you are removed from the clinical research study on which you are having the biopsies or if you are unable to follow study directions.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples or data at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they

came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

To protect your identity, the data and samples collected from you will be labeled with a unique number instead of your name or other identifying information. Only the study doctor or study staff will have access to the code that can link you to your data and samples. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

- B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.
- C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.
- E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT

DATE

PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

PERSON OBTAINING CONSENT

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people _____
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR

SIGNATURE OF TRANSLATOR

DATE

Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)