

THE UNIVERSITY OF TEXAS



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Feasibility Study of Anatomical Modeling for Image Guided Thoracic
Surgery
2019-1189

Study Chair: Ravi Rajaram, MD

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.

STUDY SUMMARY

The goal of this research study is to learn if it is possible to create a 3D model of your lung and lung nodule(s) from CT scan images performed during lung surgery.

Unlike solid organs (like the kidney, brain, and liver), the lung changes shape (they inflate when you breathe in and collapse when you breathe out). This makes it difficult to predict where, exactly, the tumor(s) will be on the lungs during surgery.

Researchers think that a 3D model may help surgeons better predict where the location of the tumor(s) will be during surgery.

This is an investigational study. The CT scan is performed using FDA approved and commercially available methods. It is considered investigational to create a 3D model of your lungs using the CT scans.

Future patients and surgeons may benefit from what is learned. There are 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 full list of potential side effects below in the Possible Risks section of this consent.

There is no cost to you for taking part in this study. You and/or your insurance provider will be responsible for the cost of your surgery.

Your participation in this study will be over after your surgery.

You may choose not to take part in this study. You may choose to have lung surgery as part of your standard care without participating in this study.

1. STUDY DETAILS

Up to 10 participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to take part in this study, you will have 4 CT scans during your lung surgery. You will be scheduled to an operating room that has the ability to perform CT scans during surgery. You will sign a separate consent form explaining your surgery and its risks, including the risks of general anesthesia (the medicine that makes you sleep during surgery).

During surgery, while you are under anesthesia, up to 5 surgical titanium clips will be placed to mark the areas that separate the lobes of your lung. The surgical clips placed will act as a point of reference on the lung and will help in locating lung lobes. After clip placement, up to 4 CT scans will be performed. The surgical technique itself is video-assisted. This is described in your surgical consent form. Video will be taken of the surgery (only video inside the lungs). No video of you, the doctor, or the study staff will be collected. This is so the surgeon can review the surgery to help build the lung model.

After your surgery, a computer will use the CT scan images to create a 3D model of your lungs later in a lab. Using a special type of software, researchers can use the models to predict how lungs inflate and deflate while you breathe and how that affects the location of the tumor(s). The CT images collected during this study will not affect your surgery and the results will not be used to change your treatment.

Your participation in this study will be over after all CT scans have been collected and your surgery is over. After your surgery, you may come back to the clinic as part of your standard post-surgery visits.

2. POSSIBLE RISKS

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of

warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

Surgical Titanium clips (markers) will be used during the surgery and will stay on the lung tissue after the CT scans are completed. Allergy to surgical titanium clips is rare, but may happen. The markers are small (about the size of a pencil-top eraser). They are made of a special type of metal that is designed to not react in your body. The clips will not set off security alarms at the airport or interfere with future MRIs.

This study may involve unpredictable risks to the participants.

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.

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. Ravi Rajaram, at 713-563-4530) 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. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Dr. Ravi Rajaram, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, 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.
9. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

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.

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

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
- 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
PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

DATE

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

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 below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

DATE