

Informed Consent/Authorization for Participation in Research

Title of Research Study: Bronchoscopic Lung Ablation of Small Thoracic Tumors: The BLASTT Registry

Study Number: 2024-1847

Principal Investigator: Roberto F. Casal, MD

Participant's Name

Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you have peripheral lung tumors that have been or will be treated with ablation via robotic bronchoscopy as part of your standard of care. Ablation is a medical procedure that destroys or removes tissue.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this data collection study is to develop a database of medical information about patients with a known diagnosis of lung cancer or metastases to the lungs who undergo robotic-assisted bronchoscopic ablation.

Researchers hope to use this information to study various outcomes (including safety outcomes), risk factors, and changes in disease imaging findings over time, as well as incorporate and analyze data collected from patients similarly treated in other institutions and collaborators.

How long will the research last and what will I need to do?

You are expected to be in this research study for up to 10 years after ablation. Data will be collected from your follow-up visits that are part of your standard of care for at least 5 years and up to 10 years after ablation.

More detailed information about the study procedures can be found under ***“What happens if I agree to be in this research?”***

Is there any way being in this study could be bad for me?

Before choosing to take part in this study, you should discuss with the study team any concerns you may have. This is a minimal risk study, and the primary risk is potential loss of confidentiality; however, measures will be taken to prevent this risk.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

There are no benefits to you for taking part in this study. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-645-2645.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 250 people will be enrolled in this research study.

What happens if I agree to be in this research?

If you agree to take part in this research, your personal health information will be collected, including, but not limited to, your demographics (including your name, date of birth, race, and so on), medical history, surgical history, treatment-related information, and disease-related information. Data will be collected from the time of ablation and at each follow-up visit that is part of your standard of care, for at least 5 years and up to 10 years after ablation.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. You may withdraw from participation in this study without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you want to stop taking part in this study, tell the study doctor.

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.

Is there any way being in this study could be bad for me? (Detailed Risks)

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.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

It will not cost you anything to be in this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

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

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is

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

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Some of your genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

What happens if I get hurt from being in this study?

This is a minimal risk study with no procedures. It is unlikely you will get hurt from taking part in this study. You may contact the MD Anderson 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.

What else do I need to know?

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

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

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 do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.
- 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.

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_____
PRINTED NAME OF PERSON OBTAINING CONSENT