VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	The CRYSTAL Study: CRYodevitalization Study for outpatient Treatment of eArly-stage Lung cancer	
Version Date:	07 August 2024	NCT06593106
PI:	Fabien Maldonado, MD, MSc	

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
As standard of care, patients in this study will undergo a procedure called a robotic-assisted bronchoscopy where a computed tomography (CT) scan of the chest is used to guide a catheter through the airways along a pathway to the nodule where samples will be collected from the tissue. If the nodule is found to be cancerous, the area will then be treated with a device through the bronchoscope called a cryoprobe that freezes the tissue which can cause the cells to die. This use of the cryoprobe is for research purposes for devitalization. Following this procedure, patients will undergo surgery for tumor removal. The tumor will be evaluated by a pathologist to determine the impact of the freezing on the tissue. The results of the study will help determine if cryotherapy from within the airways on early-stage lung cancer should be used to treat tumors which could provide patients, who cannot undergo surgery, another treatment option. This could pave the way for a possible future where patients can undergo a biopsy of a lung nodule followed by treatment in a single procedure.

The risks of this procedure and associated research study include bleeding, lung collapse (called a pneumothorax), respiratory failure, and possibly death. No additional follow-up will be need from the patient except those associated with the clinical treatment of the nodule through bronchoscopy and surgical resection.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are undergoing a bronchoscopy as

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part of your routine standard of care. The cryoprobe for treatment will only be used if our pathologist finds cancer cells on your biopsy tissue. Whether you choose to take part in this research or not, your doctor will take care of you. If you decide not to take part in the study, you will still receive the same routine care.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Side effects from peripheral nodule biopsy during bronchoscopy include cough during and after the procedure and a sore throat. Risks of the procedure include infection, bleeding from the area of biopsy, and a hole in the airway causing a collapsed lung (about 2-4%). Additional rare risks include breathing failure and death (<0.1%).

Risks that are not known:
Because this treatment is investigational, there may be risks that we do not know about at this time. This form of cancer treatment by freezing tissue has been used for many years from the outside of the chest and is associated with coughing up blood (18%), bleeding in the lung (6%), fluid building up outside the chest (called pleural effusion, 2%), and increased shortness of breath (1%). Initial data from cryotherapy from within the airway using smaller doses have shown no safety or adverse events.

Other Risks:
One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only the research study team will have access to your name.

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

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your genetic information that comes from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: The results of the study will help determine if cryotherapy from within the airways on early-stage lung cancer should be used to treat tumors and could provide patients, who cannot undergo surgery, another treatment option. This could pave the way for a possible future where patients can undergo a biopsy of a lung nodule followed by treatment in a single procedure.

Procedures to be followed:
The purpose of this study is to look at the immune response after treatment with a cryoprobe on a lung cancer nodule. The tissue from the biopsy and the surgery will be looked at to see how your body reacted to the cryoprobe treatment.

You are being asked to give samples obtained during the bronchoscopic biopsy and surgical removal of the tumor. What we learn about you from this sample may be put in your health record as part of your clinical care. The immune and genetic testing done will not be included in your medical record and may or may not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

Payments for your time spent taking part in this study or expenses:
Not applicable.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

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You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Jennifer Duke or Fabien Maldonado at [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your doctor will select the most appropriate course of clinical care. If new information on biopsy practices or lung cancer treatment were to arise that applied to you, then you would receive the appropriate treatment and would not be eligible for this study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

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A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:
Every effort will be made to protect your privacy. Your name and protected health information (PHI) will be kept confidential to the extent possible and as required by applicable laws and regulations. All records and data related to the study will be maintained in secure protected spaces. The biopsy specimens will be stored in Vanderbilt Medical Center Laboratory spaces and coded to ensure the samples are deidentified.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit because of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact [redacted] to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

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Study Results:
Not applicable, study results will not be provided to participants.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
Every effort will be made to protect your privacy. Your name and protected health information (PHI) will be kept confidential to the extent possible and as required by applicable laws and regulations. All records and data related to the study will be maintained in secure protected spaces.

Who will see, use, or share the information?
The people who may request, receive, or use your health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____