Title: Robotic versus Electromagnetic Bronchoscopy for Pulmonary LesIon AssessmeNT: (the RELIANT trial)

NCT #: NCT05705544

Document Date: 10/13/2023

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Version Date:	11/21/2022
PI:	Fabien Maldonado, MD

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:
Vanderbilt University Medical Center (VUMC) is a learning healthcare system. As part of your routine care, you will undergo a bronchoscopy with one of our two machines. At VUMC, we are studying if there is a difference between these two machines. We are studying how well our routine biopsy procedures work to biopsy lung spots. Whether you choose to participate or not, you have been assigned to one of our two standard machines to biopsy lung spots. You will receive a standard of care bronchoscopy with either machine used.

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 part of your routine standard of care. The research only involves use of the data collected in the medical record to see how good the biopsy was for guiding your care. 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 can also choose to stop taking part in the study at any time.

Side effects and risks that you can expect if you take part in this study:
Both machines have been approved for use by the FDA and are used at Vanderbilt University Medical Center. The risks of the procedures, which are being done as part of your clinical care, are described in

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your procedural consent. These are the side effects of your clinical procedure and have nothing to do with your taking part in research.

Risks that are not known:
Your doctor will select the most appropriate course of clinical care. If new information on biopsy procedural practices was to arise and one of our two machines was recommended for specific cases that applied to you, then you would receive the appropriate treatment and would not be eligible for this study.

Other Risks:
The risk involved with the research is that your information could be seen by people not part of the study. To help prevent this, data will be saved in a secure database and in a locked file cabinet. This will lower the risk of anybody seeing your information.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: the potential of better diagnosis of lung spots.

Procedures to be followed:
As part of your routine care, you will receive a bronchoscopy with one of our two machines. We are studying how well our routine biopsy procedures work to biopsy lung spots. Whether you choose to participate or not, you have been assigned to one of our two standard machines to biopsy lung spots. You will receive a standard of care bronchoscopy with either machine used.

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

Costs to you if you take part in this study:
Not applicable. There is no cost to you for taking part in this study. 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.

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

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injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury. There are no plans for Vanderbilt [or the Sponsor] to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] 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 **Fabien Maldonado** at **(615) 322-5000**.

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 were to arise and one of our two machines were recommended for specific cases 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:
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:
The risk involved with the research is that your information could be seen by people not part of the study. To help prevent this, data will be saved in a secure database and in a locked file cabinet. This will lower the risk of anybody seeing your information. You can choose not to have your data be part of the study.

Privacy:
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.

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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?
Only relevant key study personnel will have access to your data as necessary to conduct the research. Secondary use of the data will be with Institutional Review Board approval. The dataset may be made available outside of the study team on reasonable request with approval from an authorized Institutional Review Board and concurrence with the study team that the data are fit for purpose.

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?
Records will be retained compliant with institutional, federal, and local regulations. Secondary use of the data will be with Institutional Review Board approval. The dataset may be made available outside of the study team on reasonable request with approval from an authorized Institutional Review Board and concurrence with the study team that the data are fit for purpose.

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