NCT04066699

Percutaneous Localization: Open-label Registry of Thoracic Surgery (PLOTS)

IRB Approved ICF Template – 1 July 2019

IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Jul 01, 2019

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

TITLE: Intraoperative, Percutaneous Localization of Peripheral Pulmonary Nodules for Resection: a Prospective, Open-Label, Multi-Center Registry Study of Thoracic Surgery Outcomes.

PROTOCOL NO.: VMT-01-003
WIRB® Protocol #20191713

SPONSOR: Veran Medical Technologies, Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Phone Number
Phone Number (24 hours)
[24 hour number is required]

Susan Shelby, PhD
Executive Director of Global Clinical Operations
(Veran Medical Technologies, INC.)
(314) 659-8500, x204

CONCISE SUMMARY:
The use of CT to screen for lung cancer has enabled detection of lesions at increasingly smaller sizes. Yet that positive development brought along with it a clinical challenge: until recently, patients with small lesions were told that their only option was to wait until the lesion could be palpated before having it removed. Locating and marking small lung nodules (0.4 cm – 3.2 cm) is a surgical challenge. Studying localization techniques allows us to understand how to best guide surgeons to the precise location of small lung lesions, some of which are benign and some of which are pre-cancerous. Should you join this research study, we will collect information from the procedure you would have regardless of the research. The purpose of this Registry study is to collect and analyze the use of computer-guided localization techniques to mark and remove these small lung nodules. The lung surgery procedure itself is not being studied. The only research procedures are data collection.

The computer-aided technology and the associated tools are devices developed for this purpose and cleared for marketing by the FDA. There are no experimental medical procedures in this Registry. The clinical research involved is collecting data on nodule localization. These results will be analyzed to better optimize the methods of localization.

Your medical record will be reviewed to collect information about the nodule marking procedure and lung resection procedure, your nodule location and size, bronchoscopy, CT scans, X-ray studies, medications, and any other diagnoses. The risks of participation are only for the confidential use of your data. You will receive no direct benefit, but others may benefit from the information learned. Your participation will last only as long as the collection and use of the information. Participation is voluntary. Your alternative is to have your procedure without data collection for research.

If you are interested in learning more about the study, please continue reading below.

DETAILED INFORMATION

You are being asked to take part in this research study because you are undergoing lung surgery for your lung lesion. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

Dr. [Principal Investigator] will conduct the study and it is funded by Veran Medical Technologies. The sponsor of this study, Veran, will pay [Hospital or University] to perform this research, and these funds may reimburse part of Dr. [Principal Investigator]'s salary.

What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study physician or the study team to explain any words or information that you do not understand.
- You are a volunteer. You can refuse to join or join and change your mind later. Either way, there will be no penalty or loss of benefits to which you are otherwise entitled.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- Information about your study participation will be included in your medical record, which is used throughout [Hospital Name]. Doctors outside of [Hospital Name] may not have access to this information. You can ask the research team to send this information to any of your doctors.
- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

1. Why is this research being done?

The registry is aimed developing a high quality set of technical data about surgeons managing small or difficult to access lung nodules. About 40% of lung nodules lie in areas that aren't reached using a bronchoscope from inside of the chest cavity. Where the nodule is located, whether the nodule can be felt, and precisely marked with dye and or microcoils are factors in identifying the correct lung section to remove. Surgeons use hollow needles to inject dye, coils, or guidewires through the subject's skin to the location of the nodule, guided by computer imagery. These tools help the surgeon to accurately mark/locate the nodule during the following lung resection operation. The dye/coils are removed from the subject's lung with the suspicious nodule during the lung resection operation. Removal of early stage malignant nodules have the benefit of increasing mortality in early stage lung cancer and of being potentially curative. However, multicenter, prospective studies have not been reported using technologically-advanced tools.

In this study, we will record techniques used by surgeons using computer-guided techniques to aid in lung nodule identification and resection. This collective knowledge will be analyzed to provide technical information that will be shared with cardiothoracic surgeons to help inform them about the best practices in this area.

Adults with lung who have been determined to need a lung resection by a cardiothoracic surgeon may join.

How many people will be in this study?

Approximately 100 people will be enrolled in this study. The study will take place at about 13 different hospitals and medical facilities in the United States. Approximately 8-10 people will take part at [Hospital Name].

2. What will happen if you join this study?

If you agree to be in this study and are found to be eligible, we will ask you to do the following things:

- You will be asked to read and sign this consent form.
- Your personal information about your condition and procedure, before and after the procedure is done, will be collected.

The research does not affect the procedure or how it is done.

How long will you be in the study?

Your involvement in the study will last from the baseline visit prior to surgery through to the day of your discharge from the hospital (following your surgery). Depending upon scheduling, this may be as short as 10-14 calendar days, or between 6-8 weeks.

3. What are the risks or discomforts of the study?

- There are no physical risks associated with this study.
- There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Secure, password-protected

databases will be used to store study data. You may stop your participation in this study at any time.

- The procedure being performed is not part of the research.

Not Experimental

The risks and benefits of the procedure as described by your physician are identical regardless of your decision to enroll in the aforementioned study. Enrollment in this study in no way changes the methodology or protocols for management of your care during your nodule localization or lung resection procedures. Surgeons are free to use the tools and techniques they feel will be safe and effective.

4. Are there risks related to pregnancy?

This study will not enroll pregnant women. If you are a woman who is able to become pregnant, you will have a pregnancy test for clinical purposes prior to your surgical procedure.

5. Are there benefits to being in the study?

There is no direct benefit for participating in this study. We hope that in the future the information learned from this study will benefit other people with your condition.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at [Hospital Name] will not be affected.

7. Will it cost you anything to be in this study?

- You will not be charged to participate. Your procedure is not part of the research and will be billed as it would regardless of the research.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, [Hospital Name] may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- The study physician believes it is best for you to stop being in the study.
- You do not follow the directions and requirements of the study.
- The sponsor stops the study for any reason.
- You become pregnant.

- The study is cancelled.
- You have a new injury or illness.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, [Hospital Name] may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at [Hospital Name], particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of [Hospital Name] may need to see or receive your information for this study. Examples include the FDA, site safety monitors and members of the company that sponsors the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside [Hospital Name] who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the [Primary Investigator] may ask to see relevant health care records from other health care providers (for example, an earlier CT scan).

13. What treatment costs will be paid if you are injured in this study?

[Hospital Name] does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at [Hospital Name] is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form, you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is (800) 562-4789. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

You can contact your [Principal Investigator] regarding questions, concerns, or complaints about the study.

If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form.

You can contact the study sponsor, Veran Medical Technologies, Susan Shelby, PhD, Director of Global Clinical Operations (Veran Medical Technologies, INC.), at (314) 659-8500, x204.

If you cannot reach Dr. Shelby or wish to talk to someone else, **please call the IRB office at (800) 562-4789.**

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call [Name] during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call [Name] at [Phone Number] during regular office hours and call the [Name] at [Phone Number] after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?

[Hospital Name] and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, [Hospital Name] may share your biospecimens and information with our research sponsors and partners. Your identifiers might be removed from the identifiable private information and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

15. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT. A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED). A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE SENT TO THE SPONSOR COMPANY.

ONLY CONSENT FORMS THAT INCLUDE THE IRB APPROVAL DATE CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED). A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE SENT TO THE SPONSOR COMPANY.

ONLY CONSENT FORMS THAT INCLUDE THE IRB APPROVAL DATE CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2060.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Subject **Date**