Protocol Title: Percutaneous Image Guided VATS Resection of Lung Lesions

Principal Investigator: Raphael Bueno, MD

Site Principal Investigator:

Description of Subject Population:
Adults greater than or equal to 18 years of age, with a small single lung lesion, that are considered for excisional biopsy by Video Assisted Thoracoscopic Surgery (VATS). Pilot study of 25 patients.

About this Consent Form

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

++ We are doing this study to find out if intraoperative imaging can enhance and make more rapid and definitive the localization of lung nodes during surgery and enable more precise surgical resection while saving normal lung tissue. The imaging will be done in the Advanced Multimodality Image Guided Operating (AMIGO) surgical suite with CT scans to guide the excision of your lung mass.

You are been asked to participate in this study because you are scheduled for Video-assisted Thoracoscopic (VAT) treatment for your solitary lung node. In our study, an intraoperative CT imaging will be applied and will be combined and compared with the preoperative imaging to precisely locate the lesion and the surrounding area of resection.

Currently lesions/nodules are located with preoperative CT scans and intraoperatively palpated for confirmation. If the lesion is not easily located through these means, a larger resection and sometimes and open procedure is warranted.

The goal of this study is to determine if intraoperative imaging can minimize the amount of normal tissue resection and make the surgery more accurate and faster. The time that each surgery takes and the amount of radiation necessary for imaging will also be measured, with the expectation that the shortest operative time and a minimal dose of radiation will be applied.

We also want to find out if analyzing a small sample of the tissue taken from your lesion with molecular methods can predict diagnosis of the mass and in the future can avoid surgeries. The tissue will be taken during the intraoperative imaging period and before excision, and will be sent to analysis in our basic research lab (molecular and cytological analysis)

This study is made possible through support from Siemens, the company that manufacture AMIGO.

How long will I take part in this research study?

You are in this research study for the period of the procedure and its associated hospital admission period. Once you are discharged, your participation in this study is complete and we will follow-up your outcome and your out patient visits.

Your participation may be terminated by the investigator or the research team if:

- You are not schedule to have VAT treatment.
- Any unforeseen reasons/problems that arise which may interfere with your ability to follow the study protocol.
- The study might also be ended by the researchers or the study sponsor.

What will happen in this research study?

The study participant will undergo the standard of care preoperative and operative preparation for a VATS resection of a lung lesion. The surgery will be performed in an operating room with CT scan. You will be placed under general anesthesia in an operating room with imaging capabilities. A brief image of the region of interest in the chest will be generated to guide device and needle placement prior to surgery.

A needle is used to obtain tissue samples from the lung lesion using this CT imaging. These tissue samples are sent for cellular and molecular analysis. This part of the study aims to determine if needle-obtained tissue samples can adequately predict diagnosis and prognosis of lung lesions.

One or two small metallic bars will then be placed into the lung lesion, also under the guidance of CT, because the metal is easier to track than the lesion itself. After the devices are placed**,** the VATS procedure will be performed with fluoroscopy if needed to guide localization of the metallic markers, and therefore, the lung lesion. Once the lesion with the metallic implants is removed, the specimen will be sent for imaging to confirm the presence of the metallic implants and that it includes all the offending lesion. The specimen will also be sent to pathology to confirm that the correct amount of tissue was removed. The operation will then be completed and the patient will be admitted for observation and recovery.

This study is being conducted through support from Siemens. There are no plans to share any tissue specimens with Siemens, but the results of this trial, with patient de-identification, will be shared per Partners Health Care agreements and procedures.
The sponsor may use identifiable and non identifiable study information for additional research.

What are the risks and possible discomforts from being in this research study?

VATS resection for solitary lung lesions is the current standard of care and the participants of this study only qualify after they have been identified as candidates for VATS resection. The experimental portions of this study are the FNAs, the placement of the metallic marker(s), and the intraoperative use of CT. The risks from these experimental portions are considered relatively low and include the following:

- Pneumothorax: air is introduced into the space between the chest wall and the lung, but this is also part of the VATS procedure and will be treated with the placement of a temporary chest tube.
- Bleeding: a risk of any surgical procedure, which will be appropriately treated. Transfusion of blood products is not expected, but may be warranted.
- Pain/discomfort: a risk of any surgical procedure, which will be appropriately treated with pain medications.
- Infection: a risk of any surgical procedure and in the case of the lung, a possible infection is pneumonia, which will be treated with appropriate antibiotics. If a foreign object is placed, this can become a source of infection. Metallic markers are placed in this study, but this will be removed with the lung lesion during the course of the surgery..
- Risks associated with the VATS procedure, including those listed above as well as the following:

- Atrial fibrillation: an abnormal heart rhythm that can usually be managed with observation and medications.
- Persistent air-leak from the lung tissue where the lesion was removed: usually managed with observation and chest tube placement as this will heal with time.
- Respiratory failure/Acute Respiratory Distress Syndrome (ARDS): very rare but may require prolonged intubation to manage.
- Need for reoperation: also rare, but may be warranted to control persistent bleeding, if initial surgical resection was not sufficient to remove the lesion, or if another unexpected complication arises.
- Damage to nearby structures
- Need for conversion to an open procedure

- As a result of your participation in this research study you will be exposed to radiation from additional x-ray exams, including fluoroscopy and CT scans**.** The amount of radiation you will receive will depend upon your body size rather than being a fixed amount. Depending on the number of image scans taken, the amount of radiation exposure you will receive is estimated to range between 5 to 30 millisieverts (mSv)**.** A mSv is a unit of radiation dose. For comparison, everyone receives radiation exposure from natural background sources from the earth and the sky. The dose that you could receive from participation in this research study is about the same as you would normally receive in 1.5 to 10 years from these natural sources. Scientists disagree on whether radiation doses at these levels are harmful. A possible effect that could occur at doses associated with this study is a slight increase in the risk of developing cancer later in life.

What are the possible benefits from being in this research study?

- Reasonably expected benefits to the participant: accurate mass resection, saving of normal lung tissue and shorter time of surgery.
  As the aim of this study is to improve current technique for excision of lung lesions, it is possible that the patient may receive no additional benefit than having the lesion removed. This study's expected benefit to its participants, however, is improved precision in the removal of lung lesions while preserving a maximum of normal lung tissue and lung function. It is also expected that this will lead to shorter operative times as less time may be required to find/confirm the lesion location and a smaller amount of lung tissue is removed. With the improved precision, it is also expected that the VATS procedure will have a lower likelihood of converting to an open procedure and therefore, this will lead to a higher chance of smaller incisions, less pain, and faster recovery.
- Reasonably expected benefits to future patients with the disease/condition being studied, and/or to society:
  The expected benefits to future patients and society includes those stated above as well as the possible benefit of being able to determine diagnosis and prognosis of the lung lesion based on a needle biopsy obtained prior to surgical excision of the lesion.

What other treatments or procedures are available for my condition?

Other treatments or procedures that are available to treat your medical condition of lung lesions include:

- VATS resection without image guidance
- Open surgery
- Palliative care or no treatment, when appropriate

Participating in this study is voluntary and you may decline participation at any time. Please discuss all options with the research doctor before deciding on your enrollment in this study.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

Although study funds will pay for certain study-related items and services, we may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have

any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Raphael Bueno, M.D. is the principal investigator of this research study.
You can call him/her at [(617) 732-8148] [Monday through Friday, 9 AM to 5 PM].
You can also call the Thoracic Clinical Research office [617-525-8541] with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject

- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)

- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent _____ Date/Time _____

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject _____ Date/Time _____

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

Signature Date/Time

Relationship to Subject:

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult Date/Time

Subject Advocate

In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing and dating below, the subject advocate represents (or "says") that the subject has given meaningful consent to take part in the research study.

Statement of Subject Advocate

I represent that the subject or authorized individual signing above has given meaningful consent.

Subject Advocate (when required by the PHRC or sponsor) Date/Time

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter _____ Date/Time _____

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name _____ Date/Time _____

Witness to Consent of Subjects Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____
(fill in above)

Witness

Date/Time

Consent Form Version: