

**13.0 MODEL CONSENT FORM:**

**A PHASE III RANDOMIZED TRIAL OF LOBECTOMY VERSUS  
SUBLOBAR RESECTION FOR SMALL ( $\leq 2$  CM) PERIPHERAL NON-  
SMALL CELL LUNG CANCER**

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have non-small cell lung cancer which needs to be surgically removed.

**Why is this study being done?**

The purpose of this study is to test a different way of doing surgery for lung cancer in patients who have small tumors with no evidence of spread. Recent studies have questioned whether removing a larger portion of the lung containing the tumor offers much better control of the cancer than removing a smaller section of the lung. The purpose of this clinical trial is to look at whether removal of a small section of lung (called a sublobar resection) is equal to a lobectomy (a larger surgery which takes out an entire section or 'lobe' of the lung, or about one-quarter to one-half of one lung, depending on which lobe is taken out). This clinical trial will be studying the overall effects (good and/or bad) of a sublobar resection (smaller segment of your lung) compared to a lobectomy (entire lobe of your lung).

**How many people will take part in the study?**

About 1297 people will take part in this study.

**What will happen if I take part in this research study?**

**Routine Medical Tests**

The following tests and procedure must be done to make sure that you are eligible for this study. None of these tests are experimental. They are routine. Depending on when you last had them done you may need to repeat some of these tests.

- You will be asked to give your medical history and have a physical examination
- Pulmonary function tests (measures your lungs ability to take air in and out)
- Chest CT scan and x-ray, which can look inside of your chest to measure the tumor
- Your doctor may or may not decide to order a PET scan for you, which can show your doctor where a tumor is at in your body, and if it has spread

Many of these tests will be repeated during the study. If you participate in this study, some of these tests may be done more frequently than if you were not taking part in this study.

### **Treatment Plan**

If you agree to participate you will be put into one of the two study groups described below. The group you are put into will be chosen by randomization. Randomization means that you are put into a group by chance. During the surgery, your surgeon will examine your tumor and determine if it is the correct size and be sure that the cancer has not spread. Once this is confirmed the research assistant will enter information into a computer program, and the computer program will then randomly place you into one of the study groups while you are still under anesthesia in the operating room. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either of the study groups.

If you are in group 1 (often called “Arm A”) you will have a standard operation for lung cancer called a lobectomy.

If you are in group 2 (often called “Arm B”) you will have a smaller portion of lung removed.

Regardless of the type of surgery done, the entire tumor will be removed. The difference is the amount of surrounding normal lung tissue that is removed with the tumor.

CALGB researchers are interested in reviewing your CT scans and PET scans (if obtained) to see how they relate to your prognosis. Therefore, copies of your scans and reports for the next 3 years will be sent to a CALGB central imaging center for review.

### **How long will I be in the study?**

Before you have surgery on this study you will need to review and sign a separate permission form from your doctor/hospital for the surgery. If, during your operation, it is determined that you are not a candidate for randomization (if your tumor is too large, if it is not the right stage, etc.) then your doctor will decide which operation is right for you and you will no longer take part in this study. Before you have surgery your doctor will discuss what surgery will be done if the tumor does not meet the criteria for this study because of size or stage.

Following your surgery the study doctor will ask you to visit the office for follow-up exams for at least every 3 months for 1 year, then every 6 months for 1 year, and then yearly for up to 5 years. You will need to have a pulmonary function test at 6 months following surgery. Additionally, you will need to have a chest CT at 6 and 12 months after surgery, and then yearly after that for up for 5 years.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the surgery can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what followup care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

## What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects.

Both lobectomy and sublobar resection have risks associated with them. We believe that the risks may be less after sublobar resection, but it is possible they could be the same or even greater. There is a risk that sublobar resection will not be as effective at removing the cancer, which could possibly lead to a higher risk of the cancer returning. If the cancer returns, it may be less curable at that time.

You should talk to your study doctor about any side effects that you have while taking part in the study.

The risks of surgery include:

### Likely

- Air leaking from the part of the lung that was operated on
- Cough and phlegm
- Partial collapse of lung

### Less Likely

- Pneumonia
- Heart attack, heart failure, or irregular heartbeat

### Rare

- Infection in the area around the lung, wound infection or blood infection
- Bleeding
- Poor healing of the skin and/or muscles in the chest
- Blood clots in the legs and/or lung

- Difficulties breathing that may require being on a ventilator (breathing machine) for days or weeks after surgery
- Stroke and/or death
- Prolonged leakage of fluid from the chest (usually temporary)
- Possible injury to nerves that control one of the vocal cords leading to voice changes (usually temporary)
- Leakage from the suture line
- Acute lung injury (also called ARDS)

For more information about risks and side effects, ask your study doctor.

## **Are there benefits to taking part in the study?**

Taking part in this study may or may not make your health better. While doctors hope a smaller resection will be as good as the usual treatment, this has not yet been proven. The reason for this study is to investigate this possibility. We do know that the information from this study will help doctors learn more about a sublobar resection when compared to a lobectomy, as a treatment for cancer. This information could help future cancer patients.

## **What other choices do I have if I do not take part in this study?**

Your other choices may include:

- Getting treatment or care for your cancer without being in this study (examples include having surgery without being on this trial, or getting treatment other than surgery, like radiation or chemotherapy)
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

## **Will my medical information be kept private?**

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The CALGB (at both the Statistical Center, where the data is kept, and at the imaging core lab, where the scans that you had are sent)

- The National Cancer Institute (NCI) and other government agencies (and their designees), like the Food and Drug Administration (FDA), involved in keeping research safe for people.

If your doctor is participating in this study through the Cancer Trials Support Unit (the CTSU is a clinical trials mechanism sponsored by the NCI to provide greater access to phase III trials), a record of your progress will also be kept by the CTSU. If your record is used or disseminated for such purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

## **What are the costs of taking part in this study?**

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. You will not be charged for the shipment of the x-rays and scans to the CALGB central imaging center.

You will not be paid for taking part in this study.

*For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.*

*Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.*

## **What happens if I am injured because I took part in this study?**

It is important that you tell your study doctor, \_\_\_\_\_ [investigator's name(s)], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at \_\_\_\_\_ [telephone number].

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

## What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

A Data and Safety Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

## Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor \_\_\_\_\_ [name(s)] at \_\_\_\_\_ [telephone number].

For questions about your rights while taking part in this study, call the \_\_\_\_\_ [name of center] Institutional Review Board (a group of people who review the research to protect your rights) at \_\_\_\_\_ (telephone number).  
[Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]

\*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only). [\*Only applies to sites using the CIRB.]

## Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>

- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

## Signature

I have been given a copy of all \_\_\_\_\_ [*insert total of number of pages*] pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant \_\_\_\_\_

Date \_\_\_\_\_

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Sample Copy for Training Only