Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Multicenter, prospective, randomized trial of bronchoscopy with ultrathin bronchoscope and radial endobronchial ultrasound (R-EBUS) with fluoroscopy versus standard fiberoptic bronchoscopy (FB) with fluoroscopy for biopsy of pulmonary lesions

A. **PURPOSE AND BACKGROUND:**

You are being asked to volunteer for a research study. This research is sponsored by Olympus, Inc. The purpose of this study is to compare the yield of two methods for obtaining a lung tissue sample: Procedure #1: standard fiberoptic bronchoscopy (FB) with fluoroscopy, and Procedure #2: ultrathin bronchoscope procedure with fluoroscopy and radial endobronchial ultrasound (R-EBUS). These two procedures are similar in that they both: (1) enable your doctor to look inside your lungs with a device called a bronchoscope, and (2) Use fluoroscopy, which is a technique that uses X-rays to see your lungs. Both Procedure #1 and Procedure #2 are approved by the FDA and are used by MUSC doctors to see their patients' airways.

These two procedures are different in that: (1) Procedure #2, with the ultrathin bronchoscope, enables your doctor to get to additional areas of your lungs, and (2) Procedure #2 uses R-EBUS. R-EBUS is a technique that uses rotating ultrasound with the bronchoscope to help your doctor see areas on the other side of your airways more clearly. Ultrasound is the same technology used to look at babies and hearts; it uses sound waves to look at structures inside the body. With R-EBUS, the ultrasound is attached to a long thin wire. The ultrasound tip goes into the airways, and the probe on the tip rotates and allows your doctor to see what is on the other side.

You are being asked to participate in this study because your doctor would like you to get a biopsy (sample) of your lung tissue via bronchoscopy. This will give the doctor an opportunity to use either of the bronchoscopy methods described above and compare the tests to see if R-EBUS provides better results than standard bronchoscopy. The investigator in charge of this study is Dr. Nichole T. Tanner. This study is being done at six or more sites and will involve approximately 214 volunteers. We expect to enroll up to 75 volunteers at MUSC. Dr.

Tanner and MUSC will receive funds from the sponsor to administer this study.

B. **PROCEDURES:**

If you agree to participate in the study, you will get the following procedures as part of your ROUTINE MEDICAL CARE:

1. You will have a bronchoscopy, which is a procedure that allows your doctor to look into your airways and into your lungs with a bronchoscope. You will have a bronchoscopy with either a standard bronchoscope with fluoroscopy (lasting 30-45 minutes), or an ultra-thin bronchoscope with R-EBUS and fluoroscopy (lasting about 45 minutes).
2. A CT of your lungs will be done once before your procedure so that your doctor can look at it during your bronchoscopy. Your CT procedure will take about one hour.
3. Your doctor will use a brush to get a biopsy (sample) of your lung.
4. Your doctor will perform 5 transbronchial biopsies. For this procedure, your doctor will pass tiny forceps (tweezers) through the bronchoscope into your lungs to get a biopsy.
5. After your bronchoscopy, you will get a portable chest X-ray (CXR) so your doctor can check to make sure you do not have a collapsed lung.
6. If your bronchoscopy does not provide a diagnosis, your doctor may ask you to get another procedure such as a second CT-scan, another biopsy, or possibly surgery.
7. The researchers will check your medical records to gather information about the results of your Chest X-ray and your biopsies.
8. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

If you agree to participate in this study, you will undergo the following STUDY PROCEDURES:

1. You will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice of which group to which you are assigned. The two groups are Group A (Procedure#1: standard fiberoptic bronchoscopy

with fluoroscopy) and Group B (Procedure #2: bronchoscopy with ultrathin bronchoscope, fluoroscopy, and R-EBUS).
2. The information about your medical condition and your procedures will be entered into a study database. This information will be used to compare the Group A and Group B procedures' usefulness in obtaining lung tissue.

There will be a pathologist on site for the standard FB. If the standard FB does not provide a diagnosis (does not identify what kind of tissue your biopsy is), your doctor may perform R-EBUS.

C. **DURATION:**
Participation in the study will take one visit. The entire visit, including the pre-procedure preparation, CXR, and post-procedure monitoring, lasts about 4 hours.

D. **RISKS/DISCOMFORTS:**
The greatest risk from your ROUTINE BRONCHOSCOPY is from the sedation (medication to make you sleepy). There is also a small risk of collapsed lung, vomiting, dizziness, vocal cord problems, infection, low blood oxygen, heart attack, and bleeding from the biopsy site. All of these risks are rare; they occur in less than 5% of the patients who undergo bronchoscopy.
The risks from your STUDY PROCEDURES are:
1. Randomization: You will be assigned to a treatment procedure by chance. The biopsy procedure you receive may prove to be less useful than the other procedure. If you are randomized to the standard FB and a diagnosis is not obtained, you may get a second procedure (R-EBUS).
2. Loss of Privacy: There is a small risk that your medical information that we enter in the study database may not remain private.

E. **BENEFITS:**
The potential benefit to you is that the procedure you receive may prove to be more useful and provide more information to your doctor than the other standard treatment, although this cannot be guaranteed.

F. **COSTS:**
You or your insurance company will be billed for your clinic visits, and

all standard of care procedures and tests (e.g. CT scan, bronchoscopy, Chest X-ray, biopsy fees).

G. **PAYMENT TO PARTICIPANTS:**
You will not be paid for participating in this study.

H. **ALTERNATIVES:**
The alternative to participating in this study is to not participate. You would still receive bronchoscopy. You would not be randomized to a procedure but would just receive one or both procedures depending on the preference of your doctor.

I. **NEW INFORMATION**: If there are significant new findings during the course of the study, you will be notified.

J. **STUDENT PARTICIPATION:** Your participation or discontinuance will not constitute an element of your academic performance nor will it be a part of your academic record at this Institution.

K. **EMPLOYEE PARTICIPATION**: Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this Institution.

L. **SPONSOR COMMITMENT:** Neither Olympus nor MUSC assumes any responsibility for paying for costs for medical treatment that a Study Subject receives for an illness or injury which results from the Study. Should a subject injury occur, MUSC will provide medical treatment to the Subject. MUSC will bill the subject's medical insurance; however, should the insurance company deny coverage or if insurance is not available, the Subject will be responsible for payment for such costs. Your consent to participate in this research study does not take away any legal rights which you may have in the case of negligence or legal fault of anyone who is involved with this study.

M. CONFIDENTIALITY: The study doctor and staff will make every effort to keep the information stored on the study database confidential. This information is stored on a secure database stored on the MUSC secure server that can be accessed only by study personnel. All paper study-related documents will be stored in a locked filing cabinet in a locked office (CSB 809) at MUSC. Only study personnel will have access to these documents.

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.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can identify you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in the case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related

injury, I may contact Dr. Nichole Tanner (843) 792-0536. I may contact the Medical University of SC Hospital Medical Director (843)792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information, or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office or Research Integrity Director at (843)792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Signature of Participant Date