

**LUNG SCREENING STUDY  
PROTOTYPE CONSENT FORM**

**NAME OF SCREENING CENTER**

**DESCRIPTION OF STUDY**

I have been invited to take part in the lung screening study sponsored by the National Cancer Institute, LOCAL SCREENING CENTER, and other centers across the country. The purpose of this study is to determine the effectiveness of screening spiral CT (low radiation-dose computed tomography) in detecting lung cancer relative to screening chest X-ray. This study will enroll 3000 men and women who are smokers or former smokers between the ages of 55 and 74.

**STUDY PROCEDURES**

By agreeing to participate in the Lung Screening Study, I agree to be assigned by a random process to either a spiral CT group or a X-ray group. I understand that I have an equal chance of being assigned to either group.

If I am assigned to the X-ray group, I will receive a single-view chest X-ray, which is a common type of X-ray for the lungs, which will be performed at LOCAL SCREENING CENTER. I will be asked to inhale deeply and to hold my breath for a couple of seconds while the X-ray is being taken.

If I am assigned to the spiral CT group, I will receive a spiral CT scan, which will be performed at LOCAL SCREENING CENTER. Spiral CT uses X-rays to scan the entire chest quickly (in 15 to 20 seconds) during a single breath hold. During the procedure, I will lie very still on a table that will move through an X-ray machine shaped like a doughnut with a large hole. Inside the machine, the X-ray will quickly rotate, after which a computer will create a three-dimensional ("3D") model of the lungs.

By agreeing to participate in this study, I agree to have the screening test performed as required by the study. The examinations that are part of this study are tests that doctors use frequently to diagnose problems in patients with certain symptoms of lung disease. They have not been established as standard of care for early detection of lung cancer. Their effectiveness in early detection of lung cancer is being tested in this study. I also understand that chest X-ray as a lung cancer screening test is available outside this study. It is unknown if these tests will provide any benefit to me.

After I have received my results from this study, I may be randomly selected to complete a short, questionnaire. The questionnaire will ask about my recent medical care. This questionnaire will be mailed to my home with a pre-paid, pre-addressed envelope to return the questionnaire to the screening center. There will also be the name and phone number of a person to contact should I have any questions.

## **BENEFITS**

I understand that I will receive a free lung cancer screening test. I further understand that if I have lung cancer, it is possible that the cancer may be detected at an early stage. Early diagnosis may prolong my life; however, this has not been demonstrated scientifically.

## **RISKS**

I understand that there are certain risks that might be associated with the screening procedures.

- A small amount of radiation is received as part of the spiral CT. This amount is similar to the amount received from a mammogram and poses no measurable risk. A small amount of radiation is also received as part of the single-view chest X-ray. This amount is smaller than the amount received from a normal chest X-ray and poses no measurable risk.
- It is possible that the screening spiral CT or single-view chest X-ray may falsely suggest that I have cancer. In this case, it is possible that I may suffer pain, anxiety and expense that could have been avoided if I had never undergone the screening test.
- It is possible that diagnosis (and treatment) of cancers detected in this study may not prolong my life and may result in medical complications.

## **NOTIFICATION AND COSTS**

I understand screening test results will be sent to me as soon as they become available. If I have provided the name of a primary physician, he/she will receive the results. If the results indicate a potential medical problem, I will be offered a referral to a physician specialist from whom I can receive further medical evaluation, if I so choose. The costs of diagnostic tests beyond screening will not be covered by the study and are my personal responsibility.

If I am diagnosed with cancer, I may be referred to a cancer specialist, if I so request. The costs of cancer treatment will not be covered by this study.

## **COMPENSATION FOR RESEARCH-RELATED INJURIES**

In the unlikely event of physical injury resulting from my participation in this study, I will be provided with immediate medical treatment. I understand, however, that no payment for medical treatment is available from the National Cancer Institute for any such injury.

## **EXCLUDED PROCEDURES**

This study includes only the screening tests listed above. Other medical procedures are not part of this study.

## **INFORMATION ON NEW FINDINGS**

I understand that any significant new findings about screening for lung cancer discovered during the term of the study will be given to me if that information will make a difference in my willingness to continue in the study.

**CONFIDENTIALITY**

I understand that information concerning my participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable state and federal laws. Personal identifying information such as name, address, and social security number will be used only for the purposes of identifying cancer cases through state registries, including the APPLICABLE STATE REGISTRY, or locating me in future years. No individual will be identified in any report or presentation.

**RIGHT TO WITHDRAW**

I understand my participation is voluntary and that I may refuse to participate and/or withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

**PERMISSION TO REVIEW MEDICAL RECORDS**

I understand that, by agreeing to participate, I give permission for my doctors and hospitals where I have been seen to release my medical records to the study investigators.

**CONTACTS AND QUESTIONS**

I have read this form or it has been read to me and I understand its contents. Any questions concerning the research or the rights of the participants involved have been and will be answered by NAMES, TITLES, PHONE NUMBERS.

A copy of this consent form has been given to me. My signature below means that I freely agree to participate in this study.

\_\_\_\_\_  
PARTICIPANT'S NAME (PRINT)

\_\_\_\_\_  
PARTICIPANT'S SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
WITNESS SIGNATURE