

**Lung Screening Study  
Answers to Potential Participant Questions**

**Participation:**

**1. Why should I participate?**

The study is designed to determine the capabilities of spiral CT and chest X-ray technologies to detect lung cancer. In order to answer this question, the participation of many people in your community is important. By participating, you will help determine the ability of these two procedures to detect cancers.

**2. Why should I participate if I don't get the Spiral CT screening test?**

By participating you will make an important contribution to lung cancer research. Lung cancer remains the chief cause of cancer death in men and women. We don't know whether the spiral CT is useful in detecting lung cancer. To determine whether or not it is useful, it is important to compare the participants who receive the spiral CT according to the study protocol to a very similar group of study participants who receive chest X-rays. Therefore, persons who receive chest X-rays play a critical role in this study.

**3. What other hospitals are in the study?**

Six Screening Centers from different areas in the country will participate in the study. The Screening Centers include the following:

- Georgetown University Medical Center, Lombardi Cancer Research Center
- Henry Ford Health System
- University of Minnesota School of Public Health/Virginia L. Piper Cancer Institute
- Washington University School of Medicine
- Marshfield Medical Research and Education Foundation
- The University of Alabama at Birmingham

**4. I had a bad experience with the hospital/the government lately, why should I help them?**

I'm sorry that your experience was not good. However, this is a special research study sponsored by the National Cancer Institute. We are committed to making your participation in this study a positive experience. By participating in the study you are helping us to learn more about the ability of the spiral CT and chest X-ray screening tests to detect lung cancer at an early stage.

**5. How will I benefit from the study?**

We don't know if you will personally benefit but if the study shows that the spiral CT screening test is effective, then this type of screening for lung cancer may become common practice in the future. If this study shows that this screening test does not improve detection, doctors will know not to use it, saving you and others unnecessary inconvenience and expense.

**6. Are there any downsides to participating?**

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 you have cancer. In this case, it is possible that you may suffer pain, anxiety and expense that could have been avoided if you had never undergone the screening test.
- It is possible that diagnosis (and treatment) of cancers detected in this study may not prolong your life and may result in medical complications.

**Eligibility:**

**1. Am I eligible to participate in this study even though I have \_\_\_\_\_ (another serious medical problem which is not an exclusion criteria)?**

If the medical problem would not interfere with your ability to participate in the screening exam, and if it were acceptable to your doctor and to [PI] here at [SC] who is directing the study, you would be eligible to participate.

**2. If I have \_\_\_\_\_ (symptom) am I still eligible for the study?**

[If a potential participant reports a symptom, s/he should be advised to make an appointment with a doctor so that the symptom can be evaluated. The potential participant should be asked to contact the SC after the medical evaluation so that eligibility may be determined.]

**3. If I recently had \_\_\_\_\_ (lung exam), am I still eligible for the study?**

[If the screening examination was a spiral CT performed in the last 24 months, then explain to the potential participant that s/he is not eligible for the study. If it was some other test, the Coordinator might ask what the result was, and if normal s/he is eligible. If result was abnormal and s/he is currently undergoing diagnostic work up, s/he should contact the SC when results of the work up are known.]

**4. I'm (54 years old/75 years old) why can't I be in the study?**

We are sorry that you cannot participate. The best way to conduct a study like the Lung Screening Study is to examine people with a similar chance of being diagnosed with the disease under study. By including people between 55 and 74 years old, we have identified a group of people at similar risk of lung cancer.

**5. I am not a smoker, or have only lightly smoked in my lifetime, why can't I be in the study?**

We are sorry that you cannot participate. The best way to conduct a study like the Lung Screening Study is to examine people with a high chance of being diagnosed with the disease under study. By including heavy smokers, we have identified a group of people at high risk for lung cancer.

**Screening:**

**1. Who will be conducting these tests? Are they qualified?**

The tests will be conducted by qualified hospital/clinic staff: doctors, and X-ray technologists. These individuals have been trained and have experience conducting these tests.

**2. Is the spiral CT or chest X-ray painful?**

Most people do not find these tests to be painful or uncomfortable. A trained medical professional will tell you exactly what to expect before the exam is given and will work with you to ensure a pleasant experience.

**3. Will you screen my husband/wife/relative/friend?**

If your husband/wife/relative/friend is interested in participating in the study, s/he should call the recruitment coordinator [appropriate person at SC] to determine if s/he is eligible. Remember that an eligible participant has an equal chance of being assigned to either the spiral CT group or the chest X-ray group. If assigned to the spiral CT group, your husband/wife/relative/friend would receive the spiral CT test; if assigned to the chest X-ray group, your husband/wife/relative/friend would not receive the spiral CT test.

**Screening Test Results:**

**1. If my test results are abnormal, does that mean I have cancer?**

Not necessarily. An abnormal screening test result usually means that further information is needed before a diagnosis can be made. Screening tests do identify cancer, but they also identify other conditions, some of which are harmless. All participants with test results which are suspicious for cancer will be referred to their doctor for diagnostic evaluation.

**2. I don't have a doctor. Who will get my test results?**

All test results will be sent to you and to the doctor of your choice. If you do not have a doctor and you have an abnormal test result, we will be happy to refer you to a doctor here at [SC associated hospital].

**3. Can I have the results of my test?**

Yes. Your test results will be sent to you within 3 weeks of your screening exam.

**4. If something abnormal is found, do I have to go to a doctor here, or can I go to my own doctor?**

You may go to the doctor of your choice. All test results will be sent to your doctor. If you would like to be referred to a doctor here at [SC], we will be happy to give you a referral list of recommended doctors.

**5. Who will see the results of my tests?**

You and the doctor of your choice will be notified as to whether the results of your test are normal or abnormal. Results will be seen by certain study personnel. All study personnel must conform to the hospital and federal regulations regarding confidentiality. They must keep all information provided by study participants and all test results confidential.

**Diagnostic Evaluation:**

**1. Will you recommend specific diagnostic examinations if abnormalities are detected on the screening exams?**

Although we will not recommend specific diagnostic examinations, we will be happy to assist you in any way possible to obtain the best medical care. We [SC] will send a letter notifying you and your doctor as to the results of the examination. When abnormalities are detected, the letter states that we recommend that you make an appointment to discuss these findings with your doctor. Your doctor may recommend specific diagnostic examinations or refer you to a specialist who can evaluate the abnormality found on the screening examination.

If you do not have a primary care physician and would like us [SC] to provide you with a list of recommended physicians, we will be happy to do so.

**2. If my screening exam detects abnormalities, will you recommend specific doctors, if I ask, to perform a diagnostic work up?**

If the screening exams detect abnormalities and you would like us [SC] to give you a list of recommended physicians, we will be happy to do so.

**3. Will the screening center recommend specific surgeons if I ask?**

If you would like us [SC] to give you a list of recommended surgeons, we will be happy to do so.

**General Questions About Cancer:**

**1. What can I do to lower my risk of lung cancer?**

The [Health Education/Risk Reduction/\_\_\_\_\_ Clinic here at SC\Cancer Information Service at 1-800-4-CANCER] has/have information about what you can do to lower your risk of lung cancer. I'll be glad to tell you how to contact them.

**2. If I have already been diagnosed with lung cancer, do I have an increased risk of developing other types of cancer?**

I'll be happy to [make an appointment/give you the telephone number] so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area, and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**3. Do you have additional information on lung cancer?**

I'll be happy to give you the telephone number so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**4. My relative had lung cancer. Does that mean I'll get it too?**

If you have a close relative with lung cancer, your chance of having lung cancer yourself does become stronger. This does not mean, however, that you will definitely get the disease. In fact, lung cancer is a rare disease even among people with relatives who have had the disease.

If you'd like me to, I'll be happy to [make an appointment/give you the telephone number] so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**5. There's a lot of cancer in my family, that worries me.**

If you have a close relative with lung cancer, your chance of having lung cancer yourself does become stronger. This does not mean, however, that you will definitely get the disease.

If you like, I'll be happy to [make an appointment/give you the telephone number] so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**6. My relative was recently diagnosed with lung cancer. I wonder if s/he's getting the right treatment?**

I'll be happy to [make an appointment/give you the telephone number] so you can speak with \_\_\_\_\_ here at [SC associated medical center] who is very knowledgeable in this area and can answer your questions. Or you can call 1-800-4-CANCER, the Cancer Information Service of the National Cancer Institute and speak with a Cancer Information Specialist who can answer your questions.

**7. Do you have a support group for individuals who have lung cancer?**

Yes, I'll be happy to give you the name and telephone number of the contact person/I'm not sure, so I will give you the telephone number of \_\_\_\_\_ here at [SC associated medical center] who will know what support groups are available/give you the telephone number of Cancer Information Service of the National Cancer Institute, 1-800-4-CANCER. Either one can tell you what support groups are available.

**8. I think I am at high risk for cancer and I should be in the group that receives the spiral CT examination.**

For scientific reasons, assignments need to be made at random. If you choose to participate, you will have an equal chance of being assigned to either the spiral CT or to the chest-X-ray group. Please remember that at this time, it is not known whether screening with spiral CT is beneficial or not beneficial for individuals at high risk of lung cancer.