Consent for Performing Screening Scanning for Abdominal Aortic Aneurysm (AAA), Coronary Artery Disease, Lung Cancer and/or Colon Cancer

The Kirklin Clinic of the UAB Health System

Patient Name: __________________________________________

Examination Date: ______________

Explanation of Procedures

You have asked us to perform a screening CT examination on you. This document explains the tests, their risks and possible benefits to you. We also have other material describing the scans we are doing and the diseases we are testing for. If you have not already seen these materials, please ask us.

CT scanning is a routine x-ray examination that has been used for many years. However, it has been used as a screening test for coronary artery disease, lung cancer and colon cancer for only the past few years.

The following is information about each of these scans:

For the Abdominal Aortic Aneurysm Ultrasound scan:
1. No preparation is required.
2. Liquid gel will be placed on your skin and a small probe will be passed over parts of the abdomen and your sides. You may be asked to hold your breath briefly and roll on your side.
3. The entire examination usually takes less than 10 minutes.

For the Coronary Artery Calcium Scoring CT scan:
1. No preparation is required.
2. You will have EKG wires taped to your chest that will help the scanner time the x-rays with the heart beat to obtain the best images. You then must lie on your back or stomach on a CT scanner table and go through the CT “gantry” or ring. You must hold your breath for a few seconds while the x-ray scan is taken.
3. The entire examination usually takes less than 15 minutes.

For the chest CT scan for lung cancer:
1. No preparation is required.
2. You must lie on your back for a few minutes while the scan is set up and then you must hold your breath during the scan itself. The scanning itself lasts for only a few seconds.
3. The entire examination usually takes less than 15 minutes.

For the CT scan of the abdomen and pelvis for colon cancer:
1. You will need to clean out your colon before the test, meaning a change in diet and using laxatives and medications that cause frequent, liquid bowel movements.
2. A small tube will be inserted into your rectum and used to inflate your colon with air until you feel full.
3. Scans will be taken with you on your back and on your stomach. You must hold your breath for several seconds at a time while scans are being taken. Your colon will feel full during the few minutes of the examination.
4. When the test is done, you expel the air.
5. The entire examination usually takes less than 15 minutes.

**Qualifying for the CT Screening scans**

You should only have these tests if you qualify for them because of your age and other risks you may have (such as smoking for the lung cancer scan). Specifically, you will be allowed to have this scan if the following is true:

For the AAA Ultrasound scan:
1. If you are over 50 years of age.

For the Coronary Artery Calcium Scoring CT scan:
1. If you have not yet been diagnosed with coronary artery disease, AND
2. You are a man from 40-75 or a woman from 45-75.
3. If you have a strong family history of heart disease, you may receive these scans as early as the age of 30 for a man or 35 for a woman.
4. You cannot have the scan if you are pregnant.

For the chest CT scan for lung cancer:
1. You have not already been diagnosed with lung cancer (unless it has been treated for cure and there is no known recurrence), AND
2. You are a current smoker or have stopped smoking within the past 10 years, AND
3. You have at least one of the following risk factors:
   • At least a 10 pack-year exposure to cigarettes (A pack-year is the number of packs you smoke per day times the number of years you have smoked.),
   • You have had a strong occupational exposure to cancer-causing chemicals,
   • You have had a strong exposure to second-hand smoke,
   • A previous non-small cell lung cancer that has been treated for cure and there is no known recurrence, AND
4. You are between 50 and 80 years of age.

For the CT scan of the abdomen and pelvis for colon cancer:
1. If you have not been diagnosed with colon cancer, AND
2. You are age 50 or over, AND
3. You have not had a complete colon screening test (a barium enema or colonoscopy) for at least three years.
4. You may have the scan at the age of 40 or older if you have a strong family history of colon cancer.

**Risks and Disadvantages**

**Detecting a disease early may not mean it is curable or treatable:** The disease may only be found after it is too late to successfully treat. In this case, you may suffer from knowing that you have a serious disease for a longer time.

**Earlier detection can also lead to more aggressive treatment:** Aggressive treatment (such as with chemotherapy or surgery) may be done for earlier disease in the hope that it is curable. In this case, you could have more side-effects from these treatments than if you waited until the disease caused symptoms.

**A positive screening test may lead to needless operations or medical procedures that cause side-effects or even death:** There is a risk that the CT or Ultrasound scan may show findings that look like serious disease, even when no serious problem exists. It is often not possible to tell serious from harmless findings on a scan. This is a very common problem. Sometimes, the question can be answered by repeating the test several times over a period of from three months to over one year.

Your doctor may order more tests or even surgery to diagnose or treat the possible disease. You could be injured from these tests or surgery. For example, up to 4 percent of people operated on for a lung nodule may die from surgery. Also, these procedures may cost you money.

**Screening tests may miss diseases that are too small or hidden:** An examination that does not find a real problem is called a "false negative" test. This happens in every type of screening test. Sometimes, when looking back at the scan after the disease is discovered later, the disease can be seen on the first scan. However, this does not always mean that the radiologist was negligent in missing this disease, because the radiologist may have thought that the "shadow" or "nodule" would be better for the patient to leave alone rather than have more tests, or because the finding looked like a normal structure.

If a real disease was missed, you may not get the benefit of early treatment and the disease could get worse to a point where it is not curable.

**Having a screening test may cause anxiety:**
Most positive findings on screening tests (like nodules in the lung) are actually completely harmless. However, follow-up tests may have to be done for over one year to prove that. During this time, you may become upset about this uncertainty.

**The screening scan is not the same quality as a "diagnostic" CT or Ultrasound scan:**
The screening scan is designed only to look for colon cancer, lung cancer or coronary artery calcium and is NOT 100% accurate for these. Also, other types of diseases may not be seen or other tests may be needed to clarify confusing findings from the screening scan. Diagnostic scans are usually done with an injection of contrast material, with higher x-ray doses and different scanning methods to enhance the images.

**Follow-up tests and treatment can be expensive:**
While insurance is more likely to cover additional tests done after a positive screening scan, there is no guarantee that such tests or other procedures will be completely paid for by insurance.

**For the CT examination of the colon, there is a small risk of perforation of the colon:**
The risk of perforation of the colon is extremely small because only a small tube is placed in the rectum and only air is used to fill the colon. The risk is substantially less than a colonoscopy.

**If the CT of the colon shows a polyp, a colonoscopy will probably be needed:**
If a polyp is found of the CT screening test of the colon, a colonoscopy will probably be recommended to biopsy or remove the polyp. If this cannot be done on the same day, you will need to clean out your colon again. Some recommend the CT colonoscopy as a single screening test for the colon because it can both detect and treat small polyps at the same sitting. However, colonoscopy is more uncomfortable, requires sedation and has a somewhat higher risk of colon perforation.

**The screening CT scan uses radiation:**
There is only a small risk from the relatively small dose of x-rays used. This is about the same or less radiation than is used for other types of CT scans. The small chance of dying from cancer from radiation happens in about 1-3 people for every 10,000. This risk starts several years after having the CT scan.

**Benefits**
The purpose of these tests is to provide you information about your health that you may use to prevent or treat disease. However, only a small percentage of people have abnormal scans. You may not personally benefit from your receiving this scan.
Alternative Tests

There are many types of tests to detect AAA, heart disease, lung cancer and colon cancer. Some physicians don’t believe that you should use CT or Ultrasound scanning for screening for these diseases because it may lead to unnecessary tests or surgery in some people and because it may be costly with no benefit to most people who are screened. You are free to discuss these other options with Dr. Lincoln L. Berland, the Director of the CT Screening Program, with one of the other radiologists doing the CT or Ultrasound scans or with your personal physician.

Questions

If you have any questions about the examination, Dr. Berland will be glad to answer them. Dr. Berland's number is 205 934-7978.

Signatures

My signature below indicates that I HAVE READ AND UNDERSTAND THE TERMS AND WORDS WITHIN THE ABOVE CONSENT, AND HAVE HAD ALL OF MY QUESTIONS REGARDING THE CT SCAN ANSWERED TO MY SATISFACTION. I agree to have the CT scan. I will receive a copy of this consent form.

_________________________________________________________________________  Date
Signature of Participant

_________________________________________________________________________  Date
Signature of Person obtaining consent