Principal Investigator: Dr. Melissa New
COMIRB No: 15-1694
Version Date: December 26, 2018

Study Title: A Prospective Pilot Study of Lung Cancer Screening in Patients at High Risk for Lung Cancer Who Do Not Meet Current Screening Guidelines

---

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about lung cancer screening in patients who may be at high risk of developing lung cancer but not eligible for lung cancer screening using the Centers for Medicare and Medicaid (CMS) guidelines.

You are being asked to be in this research study because you may be at high risk for lung cancer but are not eligible for screening using CMS guidelines. As part of this study, we will calculate your lung cancer risk using a risk calculator that uses some demographic and health history data (age, gender, race, BMI, education, smoking history, emphysema diagnosis, family history of lung cancer, and personal cancer history).

Other people in this study

Up to 100 people from your area will participate in the study.

What happens if I join this study?

If you join the study you will also have the following tests or procedures:

- You will have a low dose non-contrasted CT chest scan;
- You will be asked to allow investigators to access your medical records including: CT scan images and pathology results if a biopsy or surgery is done for suspected lung cancer.

- Give us permission to call you or contact you by mail a year after your CT scan to see how you are doing.

You will be in this study for about one year. If you remain eligible for an additional year of participation, study personnel may offer participation at the time they contact you for annual follow up. If you chose to participate for another year, you will be asked to return for evaluation and to sign an additional consent form.

What are the possible discomforts or risks?

While on the study, you may be at risk for the following side effects. You should discuss these with your study doctor and/or your treating physician.

Risks Associated with Imaging Studies (CT Scans)
The likely (more than 20%) risks from CT scans are:

- Radiation dose from a low-dose CT scan (100 to 300 mrem), which is less than or equal to the average annual dose from natural sources of radiation (300 mrem).
- False positive CT screening results that require additional testing or evaluation or testing occurs 20-40% of the time. A false positive result means that results from the imaging study appeared to need follow up, but turned out not to be disease. Most (more than 80%) of screen detected abnormalities can be monitored with additional imaging studies (CT scans), however, sometimes a PET scan or biopsy or other invasive procedure can be recommended.
- Anxiety about evaluation of abnormal screening results.

The less likely (5-20%), but serious risks are:

- False positive results on CT that require a biopsy or other invasive procedures.
- Earlier diagnosis and treatment of lung cancer that is ineffective or unnecessary.
- Abnormal findings unrelated to lung cancer that lead to recommendations for additional testing or treatment.

Other possible risks include stress and anxiety about a possible lung cancer diagnosis.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the research team to learn more about lung cancer screening using risk calculators. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored and paid for by the University of Colorado Cancer Center.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to have the CT scan performed or read by a radiologist.

If the CT scan detects any abnormalities, you and/or your health plan/insurance company will need to cover the cost of deductibles or co-pays associated with the evaluation of these findings.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Melissa New immediately. Her phone number is 720-723-6291 .

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Melissa New. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. New at 720-723-6291. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. New with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it. The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Melissa New
12700 E. 19th Avenue, Box C272
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- University of Colorado Cancer Center, University of Colorado Hospital, who are the groups paying for this research study
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. All of the information collected about you will be stored in the Primodial database that is used to clinically manage the lung cancer screening program at the University of Colorado Hospital

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnoses, History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Signature:_____ Date: _____

Witness Print Name:_____

Witness of Signature ☐

Witness of consent process ☐