CHRISTIANA CARE HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD
CCC# 38112
APPROVAL DATE: 07/18/2018
APPROVAL PERIOD 06/30/2020
THROUGH 06/29/2021
REVISED: 09/02/2020

Informed Consent

Title of Study: *Testing Informed Decision Making in Lung Cancer Screening*
Principal Investigator: Heather Bittner Fagan, MD
Contact Phone Number: 302-660 9048
Sponsor: Delaware Clinical and Translational Research, ACCEL Program

Introduction
You have been asked to take part in a research study. Before you agree to join this study, you need to know the risks and benefits so you can make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study.

The research assistant will discuss the research study with you. Research studies include only people who choose to take part. Please take your time to make your decision and discuss it with your family, friends, and health care team as necessary. Please let the research assistant know if you have any questions and he/she will answer to the best of their ability or otherwise direct your question to Dr. Heather Bittner Fagan, the Christiana Care lead researcher of this study.

You are being asked to take part in this study because you are a smoker over the age of 55.

The person responsible for this study at Christiana Care is Dr. Heather Bittner Fagan who is the Associate Vice Chair of Research and a practicing physician for the department of Family and Community Medicine. This clinical study is solely funded by Christiana Care; however, we are collaborating with Thomas Jefferson University for support and data sharing.

Why is this study being done?
The purpose of this study is to help people make a decision regarding lung cancer screening through the guidance of a decision counselor. This study will help us understand how people make decisions about lung cancer screening and it may increase the number of people who get screened for lung cancer.

How many people will take part in the study?
About 100 people will take part in this study. Participants will be patients in primary care practices at Christiana Care Health System at Christiana practices.

What is involved in the study?
The research assistant will administer a baseline survey and shortly after schedule you an appointment with a decision counselor. During your phone call with a decision counselor, he or she will administer the Decision Counseling Program ® to help you decide whether or not to participate in lung cancer screening. Discussion from the program will ensue between you and the Decision Counselor with regard to the status of whether you want to go through with lung cancer screening or not. Your primary care physician will be notified of your decision and you will be encouraged to follow-up with your primary care physician for future discussions. In addition, the research team will access your medical records approximately 60 and 120 days after this original phone call to see if you completed lung cancer screening.

If you take part in this study, you will be asked to participate in 3 phone calls:

- Phone call #1: Answer survey about decision-making, which can be done at the same time as consent, about 15 minutes.
- Phone call #2: Decision counseling session, about 15-30 minutes.
- Phone call #3: Answer post survey about decision-making, about 15 minutes.

How long will I be in the study?
The research staff will follow patients for no more than one year.

Can I stop being in the study?
You can stop being in the study at any time. Your participation is entirely voluntary.

What are the risks of the study?
Participation in this study presents minimal risk to you. Risks may include being identified because we are using personally identifiable data.

Risks of completing a questionnaire: Some people may feel some anxiety while completing the quality of life questionnaires due to the nature of the questions asked. You may skip any question that bothers you. If you do not answer some or all of the questions, it will not affect your taking part in the study.

Are there benefits to taking part in the study?
If you agree to take part in this study, there may or may not be a direct medical benefit to you. You will gain knowledge about lung cancer screening, your eligibility and this may bring about better conversations with your primary care provider.

Instead of being in this study, you have these options:
The option to discuss your participation in this study with your primary care physician or the lead investigator is always available. If you choose not to participate, you will be encouraged to talk to your primary care physician. If you want to quit smoking, you may be referred to the Delaware Quitline.

What about Confidentiality?
Information about you will be collected for this study. Your personal health information is health information about you that could be used to identify you. This information may include demographics (such as your age, sex, height, weight), information about your health now and in the past, and other facts about you collected for the purposes of this research study. The information that will be collected will be the minimum needed to meet the goals of this research study and will be used only for the study described in this consent. If information from this study is published or presented at conferences or scientific meetings, your name and other identifying personal health information will not be used.

If you decide not to allow this use of your information, this will prevent you from taking part or continuing to take part in the research study, since the researcher needs this information to meet the study goals.

If you agree to participate in the study, you still have the right to withdraw from this study at a later time. In addition, at the time you withdraw you have the right to refuse to allow future information about you to be used for the research study. If you decide to withdraw from the study, you will be asked to tell a member of the research staff and sign a written notice (called an Acknowledgement of Withdrawal form) that you no longer allow the use of information for research purposes. Your information that has already been collected cannot be taken back and will still be used for research, but no new information about you will be used in research.

Efforts will be made to keep your personal information private. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. In addition, organizations that may look at and/or copy your research records for quality assurance and data analysis include groups such as: Office of Human Research Protections (OHRP).

Information contained in your research records may also be reviewed by the Christiana Care Institutional Review Board (IRB). The IRB is a committee that reviews research projects to help ensure that the rights of research participants are protected.

Important information will be shared with your primary caregiver or other health care professionals from Thomas Jefferson University as needed for this study and for your safety. Every effort will be made to keep your information confidential.

You have the right to see any medical information about yourself. However, while this research study is in progress, you will not be allowed to see all of the health information that is created or collected during the study. You do not have the right to review and/or copy records kept by researchers associated with the research study.

What are the costs?
There are no costs to participate in or complete this study.

Will I get paid for being in this study?
Yes, you will be paid for your participation in this study.

All participants that decide to determine their eligibility will be paid $10 ClinCard regardless of their eligibility to participate in the study. Eligible participants will receive $20.00 for your participation during the decision counseling session and another $ 20 once they have completed the 30-day post-assessment phone call, totaling up to $50 for completion of the study.

Attached will be an FAQ sheet explaining how ClinCards work and will be received

What are my rights as a participant?
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide not to take part in the study, you will continue to receive the usual medical care appropriate for your condition.

Who do I call if I have questions or problems?
For questions about the study or a research-related injury, contact the research team at 302 660 9048 or the researcher, Dr. Heather Bittner Fagan at 302-320-4110.

For questions about your rights as a research participant, contact the Christiana Care Institutional Review Board at (302) 623-4983.

Please confirm that you understand all the content of this consent form and voluntarily agree to take part in this study.

A copy of this consent form along with additional education materials about the Decision Counseling Program © and the decision-making process will be mailed to you.

Participant Name: _____

Research Assistant reading consent:_____

Date: _____

Time: _____

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