Subject's Name: _____ Date: _____

Title of Study: Incorporating Veterans' Preferences into Lung Cancer Screening Decisions – Phase 3

Principal Investigator's Name: Marilyn Schapira, MD, MPH

Version date and version number: 10/16/2020; v4

Principal Investigator's Complete VA Address: Cpl. Michael J. Crescenz VA Medical Center
3900 Woodland Ave, Annex, Suite 202
Philadelphia, PA 19104

Name of Study Sponsor: VA Health Services Research & Development Service (HSR&D)

WHY AM I BEING ASKED TO VOLUNTEER?

You are being asked to voluntarily participate in a research study because you are eligible for lung cancer screening because of current or past tobacco use. Your participation is voluntary, which means you can choose whether or not you want to take part. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study doctor and/or a member of the research team will talk to you about the research study, and they will give you this consent form to read. You are encouraged to discuss this study and consent form with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form and you will receive a signed copy.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to determine if a newly developed Lung Cancer Screening Decisions Tool (LCSDecTool) is useful to patients and their caregivers.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

You will be involved with this study for approximately 3 months. You will have 1 visit at the Corporal Michael J. Crescenz VA Medical Center (CMCVAMC) or one of the Community-Based Outpatient Clinics (CBOCs). The research visit and follow-up interview should last about 3 hours. (Up to 2 hours for baseline visit and up to 1 hour for surveys after your appointment with your doctor). We will try to schedule this baseline research visit to happen just prior to your appointment with your clinical provider. There are also two follow-up visits which will occur 1-month and 3-month after the baseline research visit that will last about 1 hour.

In addition to the CMCVAMC this study will also take place at the West Haven VA Medical Center in West Haven, CT and the Milwaukee VA Medical Center in Milwaukee, WI. We plan to enroll up to 100 Veterans at the CMCVAMC and a total of 200 Veterans from all three sites.

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ID #: 01780 Prom #: 0005

Subject's Name: _____ Date: _____

Title of Study: Incorporating Veterans' Preferences into Lung Cancer Screening Decisions – Phase 3

Principal Investigator's Name: Marilyn Schapira, MD, MPH

Version date and version number: 10/16/2019; v 2

WHAT AM I BEING ASKED TO DO?

If you agree to participate in this study, you will be asked to complete several baseline surveys. In addition, you will complete a demographic form which will include information about yourself (such as age, race, and education) and whether or not you have ever had a lung cancer screening test.

Following the survey assessments, a computer will randomly assign you (like flip of a coin) to either viewing the Lung Cancer Screening Decisions Tool (LCSDecTool) or viewing information on general cancer screening and prevention. The (LCSDecTool) is a computer-based tool that we are developing to help people decide if they want lung cancer screening. While you are using the tool (experimental or control), you will be observed by a member(s) of the study team. A member of the web development team may also observe this session to better understand how the tool will function and to assist with any questions you may have. **If you do not want someone like this to be in the room during your study visit, you should not participate in this study**.

This session will last approximately 2 hours.

We are also asking providers whose patients are involved in this study to participate in the research study. After your baseline research visit, you will meet with your provider for your scheduled clinical appointment where cancer screening may be discussed as part of your routine care. At the end of your appointment, your provider will complete a one-page "Post-Visit Provider Survey." as part of the study.

Immediately after and up to one week following the provider appointment you will complete post-viewing survey assessments. This can be done by phone and will take 60 minutes.

There are two follow-up assessments which occur 1-month and 3-month post intervention. These follow-up assessments may be scheduled and confirmed by telephone or through MyHealtheVet Secure Messaging. The use of MyHealtheVet is optional. These two follow-up assessments will be completed by telephone in which survey assessments will be completed verbally. These phone calls will last about 1 hour.

If after going through the study you have further questions about lung cancer screening, we will refer you back to your Primary Care Provider.

At the conclusion of the study, the research team will contact you and provide you with information about ongoing efforts at the VA regarding lung cancer screening. At the conclusion of the study we will mail you a letter to share summary findings of the study.

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All study procedures will be done in-person at the CMCVAMC/CBOCs or by telephone.

We will collect medical information from your medical chart for about 1 year.

For participating in the initial in-person interview and the surveys after your scheduled clinic appointment, you will receive a voucher for $50 to present to the CMCVAMC Agent Cashier. In addition, for your completion of the 1-month and 3-month follow-up by telephone, you will be mailed a check for $25 per follow-up. The total amount that you could receive for participating in this study will be $100.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?
You may feel distressed from being at increased risk for lung cancer due to smoking exposure. Therefore, it is possible that a discussion of lung cancer screening may lead to anxiety or distress. If you experience anxiety or concerns, you will be referred to your primary care physician who will be able to evaluate your level of anxiety/distress and refer you to mental counseling if needed.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?
You may not directly benefit from participating in this research study. In the future, the study may benefit others if we find that this type of tool helps people with cancer screening.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?
You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to.

WILL I HAVE TO PAY FOR ANYTHING IF I PARTICIPATE IN THIS STUDY?
You will not have to pay for any research procedures or tests that result from participating in this study.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED?
Information that will be used: During the course of this study, we will collect personal information such as your:

- name
- address
- date of birth
- social security number/medical record number
- smoking history

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We will also collect dates of previous lung cancer screening tests you have had or appointments pertaining to lung cancer screening and a history of diagnoses related to smoking or lung disease such as chronic obstructive lung disease (COPD), Asthma, lung nodules, or an evaluation for lung cancer, and diagnoses of smoking related disorders.

Your name and social security/medical record number will be used only as necessary within the CMCVAMC. But other collected private information, such as your age, sex, race, smoking history may be disclosed to the study sponsor, VA Health Services Research & Development Service (HSR&D).

If you have an accident or reaction during the course of the study, your entire medical record may be used and disclosed as clinically necessary.

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

This informed consent document will be added to your medical record.

You will be assigned an identification (ID) number that is not related to any information that could identify you. The key containing the link between the study ID number and you will be kept on a secure computer server at the CMCVAMC in a separate file from the collected data. Only the study staff will be able to link your name with the study data. The information from your medical record and the survey data without your name or other ways of identifying you will be entered into a database on a VA server.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

WHAT SHOULD I DO IF I HAVE BEEN INJURED OR EXPERIENCE A MEDICAL PROBLEM?

It is important that you tell the study doctor, Marilyn M. Schapira, MD, MPH, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person

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or call her at 215-825-5800 extension 20-3883.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you withdraw, you may be asked to return for a final study visit in order to assure your safety. You should withdraw in writing using the Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration Research form. Even if you withdraw, we can continue to use information about you that has been collected up to that point. No information will be collected after you formally withdraw in writing.

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time without your consent because the Sponsor or the Principal Investigator has decided to stop the study.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

You have read or have had read to you all of the above. Marilyn Schapira, MD, or a member of her research team has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you.

In case there are medical problems, research related injuries or questions, you have been told that you can call Dr. Marilyn M. Schapira at 215-823-5800, extension 3883, or Jason Prigge, member of research team, at 215-823-5800, extension 20-3883, during the day or Dr. Marilyn Schapira at 215-898-2022 after hours.

If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subject or you want to check the validity of the study and its personnel within the VA, you should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM Monday through Friday.

If you have concerns or complaints about the research study, you should contact the research staff involved with this study at 215-823-5800 extension 20-3883.

As a Veteran, we value your input into how research is conducted at the CMCVAMC. If you would like to offer suggestions and opinions, or if you would like to participate in future

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discussions of research in Philadelphia, please call the Research and Development (R&D) Administrative Officer at (215) 823-6020 or R&D Associate Chief of Staff at (215) 823-5893. Every reasonable safety measure will be used to protect your well-being. The CMCVAMC will provide necessary medical care and treatment for any injury that is a result of participation in this study for Veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

There will be no cost to you for participation in this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co- payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged, nor your insurance billed for research-related interventions or procedures that are required by the protocol.

You voluntarily consent to participate in this study. You confirm that you have read this consent document, or it has been read to you and that it explains what this research project is about and how and why it is being done. You will receive a signed copy of this document upon your signature.

_____ _____
Subject's Signature (required) Date (by Subject)

_____
Print Subject's Name (required)

_____ _____
Signature of Person Obtaining Consent (required) Date (by Person Obtaining Consent)

_____
Print Person Obtaining Consent's Name (required)

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