Teachable Moment to Opt-out of Tobacco (TeaM OUT): A Stepped Wedge Cluster Randomized Intervention

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INFORMATION SHEET

Teachable Moment to Opt-Out of Tobacco (TeaM OUT): A Stepped Wedge Cluster Randomized Intervention

You are being asked to participate in a research study conducted by the Health Research and Development Department of Veterans Affairs in [redacted] about your experience with your recent imaging study. You are being invited to participate in a series of surveys about your experience with that program. Participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

This research is being conducted to help us understand your experiences and feelings related to the imaging program and your satisfaction with it. We will ask you questions about how the program worked and give you the chance to voice any opinions or input you may have about the program.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you agree to participate, you will be asked to complete four surveys over the course of a year. We will ask you questions about your health history including smoking history, your understanding of the scan that you had, and communication with your primary care provider and the VA. You may choose to answer or skip any questions. The surveys will take about 45 minutes and can take place in person or over the phone with a research assistant depending on your preference.

You may also be contacted by phone to take part in two 1-hour interviews to gather further information about this topic. By completing this survey, you are giving your assent to this phone call. You will have the opportunity to opt out of the interview at a later time.

We will extract information from your medical record related to this study. This includes private health information such as dates of service, health conditions, and medications. The identifiable data collected from your medical record will not be disclosed, transferred, stored, or maintained outside VAPORHCS.

Lastly, your participation will include your permission to store your research data from this study indefinitely in Dr. [redacted] Research Repository [redacted] at the [redacted] Health Care System. This information will be de-identified, meaning that it cannot be linked back to you in any way. This information may be used for future research.

This study is completely voluntary, and you may opt out at any time. You will not receive any findings from this study. Your refusal to participate will not affect your care at VA or decisions you make with your providers.

ARE THERE ANY RISKS OR DISCOMFORTS?

We want to make sure you know about a few key risks.

There are minimal risks to people enrolled in this study. The main risk is a loss of confidentiality because of sharing of health information between members of the research team. Another possible risk of this

study may be psychiatric distress caused by the survey process and possible breach of confidentiality. We will do our best to protect your private health information.

In addition, this study involves collecting information directly from your medical record. This may include information on diagnoses, treatments, and medications. This de-identified study data will be added to a repository. The research team will make every effort to protect your information. However, a loss of privacy could occur. If there is information in your medical record you do not want shared, you should consider this risk before agreeing to take part in this study.

ARE THERE ANY BENEFITS?

You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers understanding of continuing care for patients.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information collected for this study will be kept confidential. We will follow standard VA [redacted] HSR&D security precautions. Only research staff will have access to your personal health identifiers. We will house study data on servers behind the VA firewall, in a study folder only accessible to approved study personnel. Study personnel have all completed appropriate training regarding the management and protection of protected health information.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You will receive $15 for each survey in the form of a check. We will need to access your social security number and address in order to send you these checks. Study personnel will take appropriate steps to protect your information but there is always a risk of loss of confidentiality.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with study procedures.

If you have any other questions, comments or concerns about the research, call the primary study coordinator at [redacted]. If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.