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| **Participant Name**: | **Date:** |
| **Study Title**: Tobacco Cessation Treatment Preferences among Veteran Smokers | |
| **Principal Investigator**: Sarah Wilson, PhD | **VAHCS**: Durham VAMC |

**OVERVIEW AND KEY INFORMATION**

Please read this form carefully. You are being asked to participate in this research study because you may meet criteria, including current tobacco use. This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to discuss this consent with you, please ask him/her to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is to learn more about ways to help veterans quit tobacco.

Your participation in this study will involve being randomized to one of two different treatments. That means that you have an equal chance (like a coin flip) of being assigned to either treatment. In one treatment (called Mesh), you will receive quit medication, at least 5 sessions with a quit facilitator, and supporting text messaging to help you quit tobacco (if you have a cell phone and are willing to receive messages). In the other treatment (called best practice telehealth), you will receive a referral to Quit Vet (VA's quitline for stopping tobacco), a referral for SmokefreeVET (a free text messaging program to help you quit), and information about getting quit medications. You will also be asked to complete questionnaires, interviews, and breath and saliva samples before and after treatment.

The greatest risks of this study involve experiencing withdrawal symptoms when you quit tobacco. Quitting tobacco will cause nicotine withdrawal that may lead to headaches, nausea, irritability, weight gain, difficulty concentrating, poor sleep, increased appetite, anxious or depressed mood, and craving for tobacco products.

## WHY IS THIS STUDY BEING DONE?

The study is being done to learn more about ways to help veterans quit tobacco. You are being asked to participate in this research study because you may currently meet criteria, including current tobacco use. This study is being run by Dr. Sarah Wilson.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY

| Subject Identification (Last, First, Middle Initial) | IRB Approval Date |
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Approximately 30 people will be enrolled in this study at the Durham VA Health Care System.

## HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last about 6 months, but most of your work in the study happens during the first two months or so.

## WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study you will be asked to sign and date this consent form. In the baseline session (Session 0), we will ask you a series of questions related to your mood, beliefs, medical history, quality of life, substance use, and your smoking history. This session and others may occur remotely using VA Video Connect or another approved platform. These are measures of tobacco use. Because we are interested in learning about how stopping tobacco affects health care among Veterans, we will review your computerized medical record, collecting some information about your health, including laboratory results, diagnoses, and medications.

If you are eligible to participate in the study after completing the baseline session, we will use a process like flipping a coin to assign you to one of two study groups.

**Best Practice Telehealth:** Veterans who are assigned to this group will receive a referral to Quit Vet (VA's quitline for stopping tobacco), a referral for SmokefreeVET (a free text messaging program to help you quit), and information about getting quit medications.

**Mesh Treatment Group**: Veterans who are randomly selected for the Mesh treatment group will receive all of the following: personalized recommendations for medications that can help you stop using tobacco, 5 to 7 personalized meetings with a quit facilitator to help you quit and stay quit, and tailored messages from the Annie messaging service.

A study staff member will ask you questions about medication preferences and contraindications. The staff member will also review your electronic medical record to see if you have any contraindications to medication use.

Annie is an automated, short message service (SMS) text message system designed to promote Veteran self-care. It is not designed to allow you to contact a provider in a medical emergency. If you

have a working cell phone and are willing to receive SMS text messages, we will send you messages extending through 6 months after you make a quit attempt. We will tailor the messages to you receive based on your preferences on topic, type, and frequency. You can opt out of messaging at any point.

You will then be scheduled for your first meeting with a quit facilitator within 10 days of study enrollment. Quit sessions will be individually tailored to your preferences and treatment experience. You will be offered the choice of whether to complete quit sessions in person, or using a personal telephone, a personal digital device (i.e., tablet, laptop, or desktop computer with webcam), or a VA-issued digital device (i.e., 4G-enabled tablet with webcam). If you request to use a VA-issued personal digital device, we will place a consult to Prosthetics Service to get you the device. If you use a VA device, your quit sessions may occur via VA Video Connect or another approved platform.

The Mesh treatment meetings with the quit facilitator are designed to help you get ready to make a quit attempt, make a quit attempt, and stay quit. Your treatment sessions may include topics like depression, posttraumatic stress disorder (PTSD), alcohol use, pain, weight gain, medications for helping stop smoking, and other topics. Each meeting will last 30 to 60 minutes. You will participate in 5 to 7 sessions depending on your needs and experience in quitting. These sessions may be audio recorded for fidelity purposes. Part of this treatment may involve consulting with your other health care providers at VA. We will not consult with any health care provider without your knowledge and assent. If we do consult with one of your VA health care providers, treatment-relevant health information may be recorded in the electronic medical record. One week after your quit date, your quit facilitator will ask questions designed to help us further personalize your treatment. Your information will be entered into a computerized system that will design a personal treatment. Your treatment may include additional counseling sessions or taking different medications for helping you stop. If the computer system recommends taking medications, we will discuss these recommendations with you and with your assent send these recommendations to your clinic team. All prescriptions will be managed as part of routine clinical care by your VA healthcare providers, who may choose to follow or not to follow our recommendations.

For all participants in both the Best Practice Telehealth Group and the Mesh Treatment Group, we will contact you 3 months and 6 months after your baseline session for follow-up sessions. During these return visits you will complete measurements and be interviewed. If it is safe and feasible to do

so, we will ask you to provide breath and saliva (spit) samples in person at these time points.-If we are unable to schedule an in-person visit, you may be asked to provide a breath sample via video call, and a saliva sample by mail. If you complete a breath reading via video call, we will mail a breath monitor to you, and you will then return the CO monitor to us by mail. We will pay you $50 when we receive the equipment and your saliva sample.

The VA has recently approved use of an email program that will allow us to securely email you regarding study procedures. If you are comfortable receiving appointment reminders, study questionnaires, or other study messages via email, you can give your email address to the study coordinator or your study therapist.

Your data may be stored and used for future studies without additional consent from you if identifiable private information, such as your name or medical record number, are removed.

## Future Use of Data and Contact For Future Research:

If you consent to participate in this research study, we will collect information about how to contact you in the future. We will store this contact information along with your interview results in a database called "Contact Database." This database is stored at the DVAHCS. This information will be used to determine if you may be eligible for future studies run in the Traumatic Stress and Health Research Laboratory and to contact you about participation. These future studies include studies related to smoking, posttraumatic stress disorder (PTSD), and trauma. This permission is optional. Your choice to give permission to be re-contacted or not to give permission to be re-contacted will not affect your enrollment in the current study. If you do not wish for us to keep your information, we will not contact you in the future about other studies.

I agree to be re-contacted about participating in future research studies: ☐ Yes ☐ No

Only if you grant permission, data collected from you during participation in this study may be entered into a large database called "Trauma Database." This data will be used for future research. Data will not include any identifying information, and will be stored at the DVAHCS.

I agree to future use of my data: ☐ Yes ☐ No

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## WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

There are some risks to participating in the study. First, you may have some discomfort related to quitting tobacco. Quitting tobacco will cause nicotine withdrawal that may lead to headaches, nausea, irritability, weight gain, difficulty concentrating, poor sleep, increased appetite, anxious or depressed mood, and craving for cigarettes. If your physician prescribes medications to help you quit based on our recommendation, there may be side effects associated with those medications. Your physician and/or the VA pharmacist will inform you about these potential side effects. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

If you choose to take part in this study, you are at risk for the following risks or side effects. You should discuss these with your study doctor.

## WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally benefit from taking part in this study, but your participation may lead to knowledge that will help people in the future. You may benefit from stopping tobacco use, but this benefit is not guaranteed to you.

## WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

Taking part in this study is your choice. You may choose to not participate. If you choose not to participate, you may be eligible for usual VA tobacco cessation treatments. The study team will talk to you about what those treatments are like and how to enroll.

## HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any

information that would identify you. Your identity will not be disclosed without your consent, or unless required by law. Your research records will be maintained and destroyed according to VHA records retention requirements.

All study data will be kept in a secured file to which only study team members will have access. Hard copy paper records (that is, any forms you sign) will be stored in a locked filing cabinet in the study coordinator's locked office, within this research lab at the Durham Veteran's Affairs Health Care System. Information collected during your sessions will be entered into a computerized database. This database is stored on a VA secured computer server that is password-protected, and only accessible by Dr. Wilson and her study staff. An audio recording of your interview will be stored temporarily on WebEx. The recording will be moved to a VA secured computer server that is password-protected. From there, they may be moved to an encrypted DVD that is password-protected. Only study staff members have access to the passwords that protect your information.

Access to data stored at the Durham VA Health Care System will be limited to a small number of study team members who have been trained to preserve participant confidentiality. The key linking code numbers and identifying information will be kept in a locked office in the Durham VA, and will be maintained on password-protected computers behind the VA firewall on the VA secured server.

If you are asked to provide a saliva sample, the sample you provide will be mailed to an outside laboratory to be analyzed. This sample will be identified only with a study identification number.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

## DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study. If your physician decides to prescribe you medications that are recommended by our study team, you may be responsible for co-payments for those medications.

## WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be reimbursed up to $450 for your participation in this study. You will be compensated $50 for the baseline visit and for the post-treatment visit. If you attend the 3- and 6-month follow-up visits in person, you will be paid $100 each time. If you do the follow-ups by phone, you will be paid $50 for each visit when we receive the breath monitor and saliva sample.

Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

## WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAHCS or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

## WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose to not be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose to not be in the study or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

**Withdrawal of Data for Future Use** If you agree to allow your data with information that would link the data to you to be kept for future research or for re-contacting, you can change your mind at any time. To withdraw your data, contact Dr. Sarah Wilson in writing and let him/her know you are withdrawing permission for your identifiable data to be used for future research. Dr. Wilson's mailing address is:

Durham VA Health Care System
Attn: 152, Dr. Sarah Wilson
508 Fulton Street
Durham, NC 27705

If your identifying information, such as your name or medical record number, are removed, we will no longer be able to identify and withdraw your data.

## ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Wilson may take you out of the study without your consent for one or more of the following reasons: 1) failure to follow instructions of investigator and/or study staff, 2) inability to complete study procedures, or 3) the study staff cannot reach you by telephone after multiple attempts.

We will tell you about new information that may affect your health, condition, welfare, or willingness to participate in this study.

## WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

We do not routinely send out results of the research study. However, if you would like to receive copies of any journal articles that are written using the data we gather during this study, please tell the study coordinator. They will make note, and send you a copy of any article about this study.

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## DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is funded by the Department of Veterans Affairs, and portions of the study staff members' salaries are paid by this study.

## WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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.

## WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Wilson at 919-286-0411 ext. 177914 during regular business hours or after hours. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 176926.

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## AFFIRMATION FROM PARTICIPANT

**I have read this form or it has been read to me. My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.**

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| **Signature of Participant** | **Date** |
| **Signature of Person Obtaining Consent** | **Date** |