Medical University of South Carolina (MUSC)
CONSENT TO BE A RESEARCH SUBJECT
Gain-framed messages and NRT for lung cancer screening patients

A. PURPOSE AND BACKGROUND:

You are invited to participate in a research study examining a smoking cessation intervention. Research studies are voluntary and include only people who choose to take part. In order to decide whether or not you wish to be a part of this research study investigating novel smoking cessation treatments you should know enough about its risks and benefits to make an informed decision.

The purpose of this research is to design effective smoking cessation treatments for people being screened for lung cancer. 367 subjects will be enrolled in this study at 3 sites, MUSC, VA and Yale. We plan to enroll 184 participants at MUSC/Hollings Cancer Center/VA. We will determine quit rates of study participants.

Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form. This research is sponsored by the National Cancer Institute. The investigator in charge of this study is Benjamin Toll, PhD.

B. PROCEDURES:

This study has 3 parts:

(1) an intake and randomization,
(2) a treatment phase, and
(3) a follow-up phase.

If you agree to be in this study, the following will happen:

1. Intake Procedures: Before entering the study, you will have an interview with a member of the research team that will constitute an initial eligibility screening. During this interview, we will ask you about your nicotine and alcohol use and other psychological and physical problems that you or your family members may have now or in the past, your health and smoking history, etc. The intake session may be completed in two meetings if you have a time constraint. The baseline assessments can be completed at a different scheduled time at an agreed upon public place or remotely. If you are from the MUSC Lancaster or MUSC Chester site, you will only be given the option to complete this visit remotely.

2. Treatment Phase: You will be randomly assigned (like the flip of a coin) to receive either:

A) brief smoking cessation informational handouts,
OR
B) brief smoking cessation information handouts, additional educational materials with a 2-minute long video, and a 2-week starter pack of NRT.

Each participant will be given a bag with small smoking cessation tools, such as a stress ball, in addition to the other study materials. These materials will be given to you following the completion of the intake session. If the visit is conducted in person, you will receive these at the completion of your visit. If the visit is completed remotely, these items will be mailed to you. If you are in group B, you will also be given a 2-week starter pack of NRT and may be shown a video approximately 4 minutes long. The NRT dosage given will be 21mg patch and 4mg mint flavored mini lozenges.

3. Follow-up phase: You will be met at MUSC, a convenient public location, or by phone, by a staff member to assess your smoking status. If you are from the MUSC Lancaster or MUSC Chester site, you will only be given the option to complete these visits remotely. If you report you are no longer smoking during your participation the study, we will ask to collect a biological confirmation using a breath carbon monoxide (CO) test. Breath CO is a byproduct from cigarette smoking. At this appointment, you will fill out a battery of assessments and the research assistant will ask you questions about your smoking status and alcohol use. This visit will last approximately 30 minutes.

If we are unable to contact you by phone for the follow-up appointment, we will send you a follow- up questionnaire with a self-addressed, stamped envelope. The questionnaires may also be sent via email if preferred.

C. DURATION:

The initial intake session (occurring within 60 days of your scheduled decision-making visit) will take about 30 minutes. The baseline visit will also take about 30 minutes and the follow-up meeting at 1-, 3-, and 6-months will take about 15 minutes to complete.

D. RISKS/DISCOMFORTS:

Before you decide whether you want to participate, there are some risks and

inconveniences that you should know about. These include:

a) Nicotine patch: The nicotine patch is approved by the FDA and has been available Over-the-Counter for approximately 15 years. Nevertheless, nicotine patches may cause side effects. The most common side effects of the patch are nausea, dizziness, headache and redness/irritation at the application site. Rotating application sites from day to day will generally be enough to help mild reactions but stopping the nicotine patch may be necessary for more severe conditions. Other potential side effects include high blood pressure, dizziness, insomnia, vivid dreams, and abdominal discomfort.

b) Nicotine Lozenge: The nicotine lozenge is an aid to help people to quit smoking by providing low levels of nicotine to minimize withdrawal symptoms. The nicotine lozenge is also FDA approved and has been available over-the-counter for the past 15 years. Nicotine lozenges may cause side effects. Some of the more common side effects are sore throat, indigestion, gas and nausea. These side effects can be minimized by not sucking on the lozenge and rotating the placement of the lozenge in the mouth.

c) Rating Scales and Assessments: These should add no risk.

d) Video and Printed Materials: These should add no risk.

e) Loss of confidentiality: There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

f) Randomization: The treatment you receive may prove to be less effective or to have more side effects than the other study treatments or other available treatments.

g) Unknown risks: The treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participation.

E. BENEFITS:

This study may help to engage you into smoking cessation treatment; however, this cannot be guaranteed or promised.

F. COSTS:

All study procedures including nicotine patch, and nicotine lozenge are provided by the study at no cost to you. Neither you nor your insurance company will be expected to pay for these items. Please ask Dr. Toll if you want to know more about which tests are being done

solely for research.

G. PAYMENT TO PARTICIPANTS:

All participants have the opportunity to receive $50 as compensation for your time and inconvenience after the completion of the intake assessments, $10 for both the 1- and 3- month follow-up visits, and $30 after the completion of the 6-month follow up visit. If you complete all visits, you will receive a total of $100. These payments will be delivered via email in the form of amazon e-gift codes.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES:

If you choose not to participate in this study, you may engage in clinical treatment with the Tobacco Treatment Program. The following treatments are also available over the counter at your local pharmacy: nicotine replacement therapy including the nicotine lozenges, nicotine chewing gum, or the nicotine patch. Nicotine nasal spray, the nicotine inhaler, bupropion, and varenicline are available by prescription to aid in stopping smoking.

I. Employee Participation

If you are an MUSC or HCC employee, your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

J. Withdrawing from the Study

You are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. The data collected on you to this point remains part of the study database and may not be removed.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your MUSC doctors or with MUSC or Hollings Cancer Center. You would still be eligible to receive standard therapy at the Tobacco Treatment Program.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

K. Significant New Findings

You will be notified if there are significant new findings during the course of the study.

L. Clinicaltrials.gov

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.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are

entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact the PI, Benjamin Toll, Ph.D. at (843) 876-1132. I may contact the Medical University of SC Patient and Family Care Liaison at (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Signing this document means that the research study, including the above information, has been described to you orally; that all of your questions were answered; and, that you voluntarily agree to participate.

Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____ _____

Signature of Subject Date

_____ _____

Signature of Person Obtaining Consent Date