Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Comparing the Effects of Augmented Doses of Nicotine Replacement Therapy on Quitting Cigarettes and E-Cigarettes

You are being asked to volunteer for a research study called CAN-DOSE: **C**essation with **A**ugmented **N**icotine for **D**ual use **O**f **S**moking and **E**-cigarettes" study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate a combination of self-help information and nicotine replacement medications in the form of nicotine patches and lozenges to help you quit smoking and vaping. We are trying to learn more about what dose of medication works best for those quitting multiple tobacco products.

If you agree to participate, you will first complete questionnaires pertaining to vaping and smoking histories and attitudes. Once this is complete, you will be randomly assigned (like drawing numbers from a hat) to Group A (21mg patch + 4mg lozenges), Group B (21mg + 14mg patch + 4mg lozenges), or Group C (2 x 21mg patches + 4mg lozenges). All three groups will receive an informational booklet that will provide information about how to plan and engage in a quit attempt of all tobacco products used, instructions on how to use medications, and how to contact the SC Quitline and what services are provided. You will be asked to select a quit day within the next week to start using your medications. For the next 28 days (4 weeks), you will be sent daily monitoring surveys via text message to update us on your progress. At the end of treatment (after 28 days have passed), you will complete another set of questionnaires about your progress in quitting smoking, vaping, and your attitudes. If you have quit smoking and vaping, you will be asked to provide a breath sample (carbon monoxide) to show that you are not smoking. One month after this, you'll be asked to complete these same questionnaires one final time, and if needed, another breath sample.

Participation in this study may assist you in a quit vaping and quit smoking attempt, however this cannot be guaranteed. The greatest risks of this study are from the nicotine replacement medications and loss of confidentiality. You do not have to participate in this study to receive clinical treatment for vaping or smoking cessation. Alternative treatments can be arranged through the Tobacco Treatment Program at MUSC.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are a current e-cigarette user who is also smoking cigarettes, who has expressed interest in quitting vaping and smoking. This study includes nicotine replacement medications in the form of nicotine patches and lozenges to help you quit vaping and smoking. The nicotine patch and lozenge are aids to help people to quit vaping and smoking by providing low levels of nicotine to

minimize withdrawal symptoms. The nicotine patch and lozenge are also FDA approved and have been available over-the-counter for over 20 years. Although this medication is FDA approved, the dosage of the medication used in this study is experimental. The study is sponsored by MUSC. The investigator in charge of this study at MUSC is Amanda M. Palmer, Ph.D. The study is being done at MUSC. Approximately 45 people will take part in this study.

You may contact the CAN-DOSE study at **(843) 792-1413** if you have questions about being in the study or after the study is complete.

B. PROCEDURES

If you agree to be in this study, there will be three parts: (1) an intake session, (2) a treatment phase, and (3) a follow-up phase. Each phase is described below:

1. Intake Procedures (approximately 60 minutes): Before entering the study, you will have a virtual interview (via phone call or over secure video software) with a member of the research team to make sure that you meet the requirements for this study. If you are a female of child-bearing potential, this will include asking about if you are pregnant, attempting to get pregnant, or suspect you may be pregnant. You will be asked to take a pregnancy test during this initial appointment. You will show the results of the pregnancy test by sending a photo or showing it over video to confirm that it is negative. You will then complete a set of questionnaires that will ask about your vaping and smoking history and your motivation to quit.

2. Treatment Phase (approximately 5 minutes per day for 28 days): If you are eligible for the study, you will be randomly assigned to one of three groups. This is like drawing numbers from a hat to decide what group you will be in. Neither the researchers nor you will make the choice to which group you are assigned. The three groups are Group A (21mg patch + 4mg lozenges), Group B (21mg + 14mg patch + 4mg lozenges), or Group C (2 x 21mg patches + 4mg lozenges). There is an equal chance of you being put into any of these three groups (33% chance of being in group A, B, or C).

Group A: You will receive a 4-week supply of 21mg patches and 4mg lozenges (minimum of 5 & up to 20 per day), along with instructions on how to take these medications to quit smoking and vaping. You will also be given an informational booklet that discusses how to plan and take part in a quit attempt of all tobacco products used. This booklet will also provide information regarding the SC QuitLine, a freely available public service that provides tobacco quitting counseling and medication over the phone or through mobile/web platforms.

Group B: You will receive a 4-week supply of 21mg, 14mg patches, and 4mg lozenges (minimum of 5 & up to 30 per day), along with instructions on how to take these medications to quit smoking and vaping. You may choose to wear both patches on one arm, or if it is more comfortable, you can wear one on each arm. You will also be given an informational booklet that discusses how to plan and take part in a quit attempt of all tobacco products used. This booklet will also provide information regarding the SC QuitLine, a freely available public service that provides tobacco quitting counseling and medication over the phone or through mobile/web platforms.

Group C: You will receive a 4-week supply of 21mg (2 per day) and 4mg lozenges (minimum of 5 & up to 40 per day) along with instructions on how to take these medications to quit smoking and

vaping. . You may choose to wear both patches on one arm, or if it is more comfortable, you can wear one on each arm. You will also be given an informational booklet that discusses how to plan and take part in a quit attempt of all tobacco products used. This booklet will also provide information regarding the SC QuitLine, a freely available public service that provides tobacco quitting counseling and medication over the phone or through mobile/web platforms.

In all groups: You will be asked to complete either online or paper surveys (no clinic visits) daily (less than 5 minutes each)

3). Follow-up Phase (approximately 45 minutes each [end of treatment, one-month follow-up]): Regardless of what group you are in, you will be asked to complete either online or paper surveys (no clinic visit) at the end of treatment (Day 28) and one-month follow-up (Day 56). If you report that you quit smoking, you will be asked to complete a breath carbon monoxide (CO) test (breath CO is a byproduct from smoking cigarettes). This visit can be done either in-person or virtually. If you choose to do an in-person visit, a research assistant will organize a time and place with you to perform this assessment. If you choose a virtual visit, you will be mailed a carbon monoxide monitor (iCO), which is a Bluetooth device that detects your breath carbon monoxide (CO). At a prearranged time, you will meet with a research assistant via a secure, video visit and complete the breath CO sample live. You will be sent a postage-paid envelope to return the CO monitor to us.

C. DURATION

Participation in the CAN-DOSE study will take 56 days (about 2 months), with the following contact timepoints: 1) During your intake visit, 2) at end of treatment (28 days), and 3) follow-up (4 weeks after the end of treatment).

D. RISKS AND DISCOMFORTS

Before you decide whether you want to participate, there are some risks and inconveniences that you should know about. These include:

1) Nicotine patch: Nicotine patches may cause side effects. The most common adverse effects of nicotine transdermal delivery are

- Skin irritation ranging from mild itching to a more generalized skin reaction. Rotating application sites from day to day will generally be enough to help mild reactions.
- Dizziness
- Insomnia
- Vivid dreams
- Abdominal discomfort (upset stomach)
- Headaches

Because this study involves trying a higher dose of the nicotine patch, your risks of experiencing these side effects may increase. You will be asked about your side effects in the daily surveys. If you have any side effects from the patch, you can also call the CAN-DOSE study at **(843) 792-1413** at

any time to discuss your symptoms. The coordinator may work with the MUSC Tobacco Treatment Program Clinical Pharmacist, Dr. Emily Ware, to provide you with suggestions for modifying your dose or how you take the medication. You may discontinue using the medication and still remain in the study.

To dispose of the patch, remove it from your skin, fold it in half, and dispose in a secure trash can. Even if the patch has been used, nicotine exposure could be toxic to pets and children if they chew or touch the patch. Keep all patches (used and unused) away from pets and children. Avoid using your e-cigarette or smoking while wearing the patch.

It is recommended that you do not wear the patch while you vape or smoke, as this increases your risk of side effects. However, if you slip, it is not recommended that you remove the patch unless you are having severe side effects. Keeping the patch on will increase your chance for staying away from vaping and smoking by reducing your physical cravings and withdrawal. If you take it on and off, you may have a harder time quitting. Therefore, if you vape or smoke while wearing the patch, the best thing to do is to try and stop vaping or smoking as quickly as possible.

2) Nicotine Lozenge: Nicotine lozenges may cause side effects. Some of the more common side effects are:

- Sore throat
- Indigestion
- Gas
- Nausea

These side effects can be minimized by not sucking on the lozenge and rotating the placement of the lozenge in the mouth. If excess saliva is built up then the user may spit out the excess saliva instead of swallowing it. Side effects are uncommon and serious side effects are very rare. Avoid using your e-cigarette or smoking while using lozenges.

You will be asked about your side effects in the daily surveys. If you have any side effects from the lozenges, you can also call the CAN-DOSE study at **(843) 792-1413** at any time to discuss your symptoms. The coordinator may work with the MUSC Tobacco Treatment Program Clinical Pharmacist, Dr. Emily Ware, to provide you with suggestions for modifying your dose or how you take the medication. You may discontinue using the medication and still remain in the study.

3) Pregnancy Risks: Due to potential risks, you should not use nicotine replacement therapy (i.e. patches, lozenges) if you are pregnant. You will not be able to participate in the study if you are pregnant. It is recommended that you use an effective contraceptive method. Acceptable methods of birth control include abstinence, the birth control pill, intrauterine device, injection of Depo-Provera, Norplant, tubal ligation, and barrier methods such as condoms or the diaphragm. You must tell the study team if you change from your birth control plans, or if despite your plans, you think you may be pregnant. You should not use the nicotine lozenge if you have had any of the following medical conditions: heart attack, heart rhythm problems, chest pain, unmanaged severe high blood pressure, blood clots, or medical conditions in which consumption of phenylalanine is contraindicated.

4) Loss of confidentiality: There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. The research team will be taking every required precaution to ensure that your personal information is protected, which includes using secure storage of information and only using your personal information when absolutely necessary.

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

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

You will receive treatment to help with quitting e-cigarettes and quitting smoking. This study may help to engage you in a quit vaping and smoking attempt, however this cannot be guaranteed or promised.

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

G. COSTS

The SC QuitLine is considered a free service available to the public, meaning you would have access to this service even if you did not participate in this study. The cost of nicotine replacement will be covered by the study.

For the text-messaging portion of the treatment (study surveys), you will incur your normal cellular charges for sending and receiving text messages based on your cellular plan. You may opt to instead complete your surveys via email.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $25 at each of the intake, end of treatment, and follow-up assessments. You can also earn up to $60 more for daily survey completion (biweekly payments as follows: $10 for 1-4 completed, $15 for 5-6, $20 for 7-11, $25 for 12, $30 for 13-14). You will be compensated with $20 for each CO breath test sample provided (up to 2). If you complete >85% of assessments, you will receive a bonus payment of $25. The maximum that you can earn if you complete all aspects of the study is $200.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

Assessment payment schedule

# of Assessments Completed in 2 weeks	Amount paid (Bi-weekly)
1-4	$10
5-6	$15
7-11	$20
12	$25
13-14	$30

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.

I. 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. If you would like to pursue an alternative treatment rather than participate in this study, please let us know and we will help you arrange these services.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

If you would like to know about the results of the study once it is completed, you may contact Dr. Amanda Palmer by calling 843-792-1413.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

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.

P. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Q. MUSC STANDARD INFORMATION

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 study PI, Amanda M. Palmer, Ph.D. at (843-792-1413). I may contact the Medical University of SC Patient and Family Care Liaison (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.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

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Signature of Participant Date