Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Development and Evaluation of a Brief Behavioral Activation Mobile Application for Nicotine Vaping Cessation Among Adolescent Primary Care Patients (RCT)

If participants include those under 18 years of age: 1) The subject's parent or legal guardian will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides his/her assent. 3) In the statements below, the word "you" refers to your child or adolescent who is being asked to participate in the study.

Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate a mobile application (app) called "VapeX" to help older adolescents quit vaping nicotine. VapeX was developed by our research team to assist with quitting vaping.

If you agree to participate and are one of the first 5 participants enrolled, you will be assigned to the VapeX group for usability testing. The remaining 98 participants will be randomly assigned to either download the mobile app, "VapeX", or not. You will have a 1:1 chance of being assigned to each group respectively.

You will be asked to complete electronic questionnaire measures throughout the study period. Questionnaires will assess nicotine vaping, symptoms of depression, as well as your experiences using VapeX. In addition to these electronic questionnaires, if you are provided with VapeX, our study team will collect data regarding your use of VapeX. Participation in this study will take about 4 weeks, beginning the day you enroll in the study.

Participation in this study may help in the treatment of future individuals who vape nicotine. The greatest risks of this study include frustration, worsening of emotional distress, data breach, and/or loss of confidentiality. Alternative treatments include behavioral therapy for quitting vaping, which we suggest you discuss with your primary care provider.

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

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent document carefully and take your

time deciding whether you would like to participate. The purpose of this study is to evaluate a mobile application (app) to help older adolescents stop nicotine vaping called "VapeX." VapeX was developed by our research team to assist with quitting vaping nicotine as well as with the treatment of depressed mood. VapeX includes strategies for preparing to quit vaping nicotine as well as tools for improving mood. Our research team plans to commercialize VapeX in the future. Participants in this study will not share in any commercial profit of the app in the future. You are being asked to participate in this study because you reported that you are currently vaping nicotine and may be experiencing elevated symptoms of depression. The investigator in charge of this study is Dr. Jennifer Dahne. The study is sponsored by a grant from the National Institutes of Health. Portions of Dr. Dahne's and her research team's salaries may be paid by this grant. The study is being done at one site. Approximately 106 people will take part in this portion of the study, at the Medical University of South Carolina (MUSC).

B. PROCEDURES

If you agree to participate in this project, the following will happen:

1. Agreeing to be in this study will allow the research team access to information you provided during your screening to be used for research purposes.
2. Parents/guardians will **not** be informed about their child's substance use and data collection is confidential with the exception of any acute safety issues (e.g, suicidality, abuse).
3. You have already completed preliminary screening for eligibility. Final study eligibility will be determined on the day you enroll. If you do not meet final eligibility, you will still be compensated for your time.
4. If you are one of the first 5 participants enrolled, you will be assigned to the VapeX group for usability testing. The remaining 101 participants will be randomly assigned into one of two groups. You will not have the opportunity to choose which group you are in. You have a 50/50 chance of being assigned to either Group A (the *control condition*) or Group B (the *experimental condition*).
5. If you are randomly assigned to Group A (the *control condition*), you will be provided with educational material about quitting vaping nicotine and it will be suggested that you discuss any questions about mood management and about quitting vaping with your primary care provider. The educational material is from the National Cancer Institute's SmokeFree Teen website and includes information on recognizing reasons for quitting vaping, avoiding dual use of e-cigarettes and other tobacco products, setting a quit date, understanding triggers, and accessing social support.
6. If you are randomly assigned to Group B (the *experimental condition*), you will be asked to download VapeX to your smartphone. VapeX focuses on mood management as well as on quitting vaping nicotine. You will be asked to use VapeX regularly, at least once per day, for the study duration. VapeX is experimental and private health information will be collected within VapeX.

7. All participants will be asked to complete questionnaire measures throughout the study period. You will be asked to complete these questionnaires on the day you enroll and once per week over the next four weeks. You will be e-mailed and/or text messaged (based on your preference) a link to complete these questionnaires and we request that you complete the questionnaires within 24 hours of receiving the link. You will be compensated for completion of the questionnaires if they are completed within 72 hours of receiving the link. Questionnaires will assess symptoms of depression, recent nicotine vaping, as well as your experiences using VapeX, if you were randomized to Group B and received the application. It is very important that all research assessments are completed honestly and you should take sufficient time to read each assessment and respond accurately.
8. If you are in Group B, the study team will also collect information regarding your use of VapeX during the study period. This data will be collected in the background and you will not be asked to do anything for the study team to access these data. Examples of things that the study team will assess include how frequently you use the app, for how long you use the app, and what components of the app you use.

C. DURATION

Participation in this study will take about 4 weeks, beginning on the day you enroll in the study. Participation includes completion of weekly online assessments, which each should take 20 minutes to complete. If you download VapeX as part of the study, we will ask that you use it at least once per day for at least 5 to 10 minutes at a time.

D. RISKS AND DISCOMFORTS

1. **Frustration:** You will complete questionnaires throughout the duration of this study. The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer. Similarly, if randomized to Group B, you may become frustrated while using VapeX. To reduce this risk, we invite you to contact us via phone or e-mail to troubleshoot difficulties with the app.

2. **Emotional Distress:** Your depressive symptoms may become worse throughout the course of this study. Depressive symptoms will be monitored weekly by the Principal Investigator. Should your symptoms of depression worsen, or should you have thoughts of harming yourself throughout the study, the Principal Investigator will contact you via phone and will provide referrals for local mental health resources for depression treatment. The Principal Investigator will suggest that you seek treatment and then will follow-up with you via phone one week later. In the event that you report suicidal ideation during study assessments, the Principal Investigator will complete a risk assessment with you over the phone. The Principal Investigator will ask you questions about your thoughts of harming

yourself, including a likelihood of harming yourself imminently and a plan for committing suicide. If you report an imminent likelihood of harming yourself or a plan for committing suicide, the Principal Investigator will call emergency services and will remain on the phone with you until emergency services arrives. In the event that you experience clinical deterioration, you will be allowed to continue in the trial.

3. **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.

4. **Data breach:** There is a risk of a data breach of health information from the VapeX servers during the course of the study. In the event of a data breach, all app users will be notified via email.

5. **Confidentiality:** There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Efforts will be taken to ensure that all information you provide throughout the course of this study is kept confidential. In order to ensure confidentiality, all participant information will be identified with a number and kept under lock and key or on a secure MUSC server accessible only to our study team. Your information may be shared with representatives of the Medical University of South Carolina or governmental authorities if you or someone else is in danger or if we are required to do so by law.

E. MEDICAL RECORDS

If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. BENEFITS

There is the potential benefit to participants that the treatment they receive may prove to be more effective than other available treatments for quitting vaping, although this cannot be guaranteed. It is hoped that the information gained from this study will help in the treatment of future individuals who vape nicotine.

G. COSTS

Your normal cellular data usage and rates will apply while using VapeX. There are no other costs to you associated with participating in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated via electronic gift cards (e.g., Amazon), which will be emailed to you for your participation in this study. If you are under the age of 18, payment will be made to you, not to your parent or guardian. You will be paid $20 for completion of each set of study questionnaires completed within 72 hours of receiving the emailed/text messaged link to complete the questionnaires. If during the baseline visit, you do not meet final eligibility, you will still receive the $20 for your time but will not be enrolled. You will also receive a $50 bonus for completing all study questionnaires. Additionally, if you refer someone to the study that is eligible and enrolls, you will receive an additional $40. Total compensation is up to $190 for completion of all aspects of the study.

Baseline	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Bonus for completing all surveys**	**Referral**
$20	$20	$20	$20	$20	$50	$40
Total Compensation = $190						

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

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at MUSC. If you decide to withdraw, we ask that you contact Dr. Dahne to let her know that you are withdrawing from the study. Alternative treatments for quitting vaping include behavioral therapy, which we suggest you discuss with your primary care provider.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if there is evidence of fraud within completed surveys. Fraud may include

completion of study assessments more quickly than would typically be expected and/or suspicious responses to study assessments.

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

Clinically relevant research results, including individual research results, will not be disclosed to you as a part of this study.

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.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. 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.

N. 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.

O. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website 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.

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 for paper consents, or scroll down and select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

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 investigators associated with this study, the sponsor, 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 that your child is injured as a result of participation in this study, you should immediately take your child 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 your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to your child 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 your child.

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. 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 child's participation in this study or study related injury, I may contact ***Dr. Jennifer Dahne at 843-876-2280***. 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 about my child's rights as a research subject in this study, 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.

If you wish to participate, you should sign below or if consenting electronically scroll to the bottom of the screen and sign.

_____ _____
Signature of Person Obtaining Consent Date *Printed Name of Minor Participant

_____
Signature of Adult Participant Date

_____
Signature of Participant's Personal Representative (if applicable) Date

_____
Printed Name of Personal Representative (if applicable)

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian*
____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

*For Minors 12-17 years of age: "My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____