Title: Effects of Electronic Cigarette Settings and Liquid Concentrations in Cigarette Smokers and Electronic Cigarette Users

NCT #: NCT03710590

Document approval date: 06/17/2020

Document Type: Informed Consent Form

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Effects of Electronic Cigarette Settings and Liquid Concentrations in Cigarette Smokers and Electronic Cigarette Users

VCU INVESTIGATOR: Alison Breland, PhD, Assistant Professor of Psychology

SPONSOR: National Institutes of Health/Food and Drug Administration

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

The purpose of this research study is to find out how different types of electronic cigarettes settings, combined with e-liquids of differing nicotine concentrations, affect blood nicotine levels, use behavior (how you puff), and how you feel.

The results of this study will be used to help us better understand how electronic cigarette settings and liquid concentrations affect blood nicotine levels, use behavior, and how you feel.

In this study, you will be asked to do the following things:

1. Visit the Clinical Behavioral Pharmacology Laboratory/Center for the Study of Tobacco Products 6 times for approximately 4-hour study visits, which must be separated by at least 48 hours, and which will not occur more than two times per week.
2. Before each visit, abstain from **all** tobacco products for at least 12 hours. In addition, the use of any other nicotine-containing products (like e-cigarettes, nicotine gum or the nicotine patch) is prohibited. We will ask you to take a simple breath test to make sure that you have complied with these restrictions. Our tests are not perfect, but they are the only measures that we can accept to make certain that you have complied with the no tobacco/no nicotine restrictions.
3. We will also ask you to abstain from caffeinated beverages for 1 hour before each session.
4. During the study sessions, we will ask you to turn off your cell phone for the duration of the session.

5. Each session will begin with a one hour waiting period during which you will sit in the session room to allow you to get used to the setting. During this waiting period you will not be allowed to use your phone, however, we will provide you with a movie to watch or magazine to read.
6. After this 1-hr waiting period, a nurse will insert an IV catheter into your arm that will stay there for the entire session. This catheter will be used to draw blood periodically (less than 1 tablespoon per sample, 4 samples). We use this method because participants tell us that it is more comfortable than repeated "sticks" with a needle. During each session we will take much less blood than the amount you would give in a single donation at a blood drive. Inserting a catheter can be challenging for some individuals with smaller veins or veins that are harder to see. In this laboratory we will attempt to insert a catheter no more than three times in one day and, if all three attempts are unsuccessful, we will discontinue the session and pay you for the time that you spent complying with study conditions before the session began ($15) and also for the time you spent in the laboratory ($15/hour).
7. During each session, we will also monitor your heart rate (with a device that attaches to your finger) and blood pressure (with a blood pressure cuff on your arm) and ask you to respond to several questionnaires to measure how you feel before and after you use an e-cigarette.
8. During each session, we will monitor the carbon monoxide levels in your breath several times with a simple test in which we will ask you to blow through a tube.
9. In each session, you will receive an e-cigarette loaded with e-liquid that contains nicotine. For each session, you will not know the concentration of nicotine in the e-liquid, or the e-cigarette settings being tested in that session. This is called blinding, and it is done so that a fair evaluation of results may be made. During the session we will ask you to use the electronic cigarette we provide at two separate times. The first time, we will ask you to take only 10 puffs, and we will tell you when to take each of these puffs. The second time we will ask you to use the e-cigarette however you'd like. At each of these two times we need you to remain seated in a comfortable chair while you are using the e-cigarette.
10. When you use the e-cigarette, you may notice that it is connected to a computer and that there are pieces of equipment attached to the e-cigarette. The computer and this equipment are measuring how you are using the e-cigarette (the size and number of the puffs that you take).
11. There may be rare instances in which the equipment we use malfunctions during a session. If this happens, we may stop the session and ask you to return on another day to repeat that session. In these instances, if the equipment malfunctions in the first half of the session, we will pay you half of the money you would have earned in that session. If the equipment malfunction occurs in the second half of the session, we will pay you the full amount for that session.
12. At the in-person screening visit (this visit), we will ask you to provide a urine sample that we will test for nicotine (to confirm that you use tobacco products) and pregnancy (women only). If you are an e-cigarette user, we will also ask to take picture(s) of your e-

cigarette device and liquid at this visit. Also, at this visit, we will ask to see a form of identification with your date of birth. This is to verify your age.

Your participation in this study will last up to 24 hours. Approximately 136 individuals will participate in this study.

This study will not use your samples to sequence all or part of your DNA.

WHAT ALTERNATIVES ARE AVAILABLE?

This is not a therapeutic study. You have the alternative not to participate. If you do not feel comfortable answering questions on the computer, paper forms are available.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

There are both risks and benefits of participating in research studies.

Most Common Risks and Discomforts	Benefits to You and Others
1. You may experience some discomfort during abstinence from cigarettes and nicotine before the session or while using electronic cigarettes during the session. Side effects from products that contain nicotine can include sweating, lightheadedness, dizziness, nausea, and nervousness. These effects are less likely in individuals who use nicotine-containing products regularly. In addition, some people who use e-cigarettes have reported experiencing seizures. Some of these individuals reported a prior history of seizures or using other substances at the same time as their e-cigarette. 2. In some cases e-cigarette use has led to respiratory illnesses such as difficulties breathing, shortness of breath, cough, and/or chest pain before hospitalization. In some cases, e-cigarette use has led to death, although most of these cases have been related to vaping THC. In some cases symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, or fevers or fatigue have been reported. The	This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better understanding of e-cigarettes.

Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for use by by youths, young adults, or women who are pregnant. Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. If you use e-cigarette products, monitor yourself for all of these symptoms and promptly seek medical attention if you have concerns about your health. 3. The e-cigarette liquid that we give you may contain more nicotine than you usually use, although some e-cigarette users report using these liquids. Inform the study staff immediately if you experience any discomfort. 4. On very rare occasions, you may experience small droplets of liquid during inhalation of the electronic cigarette we provide. You may find these droplets to be unexpected and/or unpleasant. This experience has been reported by electronic cigarette users, and they report that it is an annoyance that does not appear to present any known medical danger. If this occurs, we will immediately replace the electronic cigarette device you are using. 5. Side effects from tobacco/nicotine abstinence can include irritability, anxiety and restlessness, excessive hunger, difficulty concentrating, and sleep disturbance. These are common abstinence symptoms in cigarette smokers. Though uncomfortable, these feelings are not medically dangerous. 6. You may also feel some discomfort when the nurse inserts or withdraws the needle, or when blood samples are taken. We try very hard to minimize your discomfort at these times, and the use of a trained nurse and sterile, disposable equipment enhances comfort while	

reducing the risk of bruising and infection. 7. Your heart rate and blood pressure may increase; if either increases above acceptable limits, your participation may be stopped for your safety. 8. You may find the monitoring equipment uncomfortable. 9. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study. 10. The use of e-cigarettes involves risks that are currently unknown or unforeseeable. Using e-cigarettes may involve risks to a developing embryo or fetus that are currently unknown. **Non-Physical Risks:** 11. Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you. 12. The study questionnaires ask personal questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.	

In general, we will not give you any individual results from the study.

Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $10 for completing the initial screening visit. You will be paid for the time that you are not using tobacco prior to session and for your time in the laboratory: you will receive $50 after the first session, $75 after the second, $100 after the third and fourth, $150 after the fifth sessions, and $175 after the sixth session. In all, you can earn $660 for completing this study. All payments will be in cash.

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by

federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study before the final regularly scheduled visit, you will be able to keep any money that you earned in the study up to that point.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU has established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

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 Website will include a summary of the results. You can search this Web site at anytime.

Samples that you provide in this study may be used to develop new tests, drugs, or other products for sale (commercial profit). You will not get any payment or share in this profit.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, contact:

Dr. Alison Breland or Dr. Thomas Eissenberg at (804) 827-3562 or at abbrelan@vcu.edu or teissenb@vcu.edu

The medically responsible investigator is Dr. Thokozeni Lipato (thokozeni.lipato@vcuhealth.org).

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date