Title: Assessment of Two New Electronic Cigarettes in Cigarette Smokers

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# RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

**STUDY TITLE:** Assessment of Two New Electronic Cigarettes in Cigarette Smokers

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**SPONSOR:** National Institute on Drug Abuse/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 not to 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

### Why is this study being done?

The aims of this study are to better understand how different types of electronic cigarettes affect blood nicotine levels and how you feel.

You are being asked to participate in this study because you are a current cigarette smoker. Approximately 30 individuals will participate in this study.

### What will happen if I participate?

For this study, you will be asked to visit the Center for the Study of Tobacco Products four times for study visits. Each visit lasts about 4 hours.

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

1. Fill out questionnaires about your health, smoking history, cannabis and alcohol use
2. Take a pregnancy test (to see if you meet criteria to be in the study)

In this study, you will be asked to do the following things prior to or during each study visit:

1. Abstain from tobacco and caffeine use prior to visits
2. Take breath tests throughout study visits
3. Have an IV catheter inserted into your arm during each study visit
4. Wear a heart rate device on your finger and a blood pressure cuff on your arm during each study visit
5. Respond to questionnaires to measure how you feel before and after you use the study product
6. Use the tobacco products during each study visit

During each study visit, you will use a different tobacco product. In each session, you will receive either an e-cigarette or your own brand cigarette. The two e-cigarettes you will use are both marketed tobacco products. During the session we will ask you to use the product 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 product however you'd like.

Your participation in this study will help us understand how people use tobacco products and e-cigarettes and what effects these products produce. You will have an opportunity to experience all of the questionnaires and see all of the equipment before your first session.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

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

**What alternative treatments or procedures are available?**
This is not a therapeutic study. You have the alternative not to participate.

**What are the risks and benefits of participating?**
There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

**RISKS AND DISCOMFORTS**: You may experience some discomfort during abstinence from cigarettes and nicotine before the session or while using tobacco products/electronic cigarettes during the session. 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. Side effects from products that contain nicotine can include sweating, lightheadedness, dizziness, nausea, vomiting, and nervousness. These effects are unlikely in individuals who use nicotine-containing products regularly. In addition, some people who use e-cigarettes have reported experiencing seizures. You may also feel some discomfort when the nurse inserts or withdraws the needle, or when blood samples are taken. It is also possible that you might feel uncomfortable answering some of the questions we ask. You do not have to answer any question that you feel uncomfortable answering. There is also a risk of a loss of confidentiality.

**BENEFITS TO YOU AND OTHERS:** You may not get any direct benefit from this study, but the information we learn from people in this study may help us to better understand the effects of tobacco products/e-cigarettes.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. 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.

**WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?**

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

If you agree to join the study, you will be asked questions about your general health, smoking history, and marijuana and alcohol use. If you are a woman you will need to provide a urine sample that will be tested immediately for pregnancy. If you are pregnant you cannot participate in this study. All of your responses will be confidential.

If the urine tests and your answers to our questions indicate that you fulfill the entry criteria, we will ask you to participate in three, approximately 4-hour sessions here at the Clinical Behavioral Pharmacology Laboratory or the Center for the Study of Tobacco Products Laboratory, located on VCU's campus. The three sessions will begin at approximately the same time each day, will be separated by at least 48 hours, and will not occur more than two times per week. Before each session, we will ask you to abstain from all tobacco products for at least 12 hours. We will also ask you to abstain from caffeinated beverages for 1 hour before each session. 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. Also, during the study sessions, we will ask you to turn off your cell phone for the duration of the session.

Each session will begin with a one hour waiting period during which you will sit in the session room to allow you to get acclimated 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. After the 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 per session). We use this method because participants tell us that it is more comfortable than repeated "sticks" with a needle. During this 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). You will also provide additional breath tests during the session before and after using the e-cigarettes or your own brand cigarette.

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 the study product.

During each session, you will use a different product. In each session, you will receive either an e-cigarette or your own brand cigarette. The two e-cigarettes you will use (JUUL and iQOS) are both marketed tobacco products. During the session we will ask you to use the product 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 product 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 product.

Your participation in this study will help us understand how people use tobacco products and e-cigarettes and what effects these products produce. You will have an opportunity to experience all of the questionnaires and see all of the equipment before your first session.

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

You may experience some discomfort during abstinence from cigarettes and nicotine before the session or while using tobacco products/electronic cigarettes during the session. 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. Side effects from products that contain nicotine can include sweating, lightheadedness, dizziness, nausea, vomiting, and nervousness. These effects are unlikely 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. 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. If you find any effects or data collection procedures unacceptable, you may stop your participation at any time. You should not donate blood 4 weeks before or 4 weeks after this study.

**Non-Physical Risks**

It is possible that you might feel uncomfortable answering some of the questions we ask. You do not have to answer any question that you feel uncomfortable answering. There is also a risk of a loss of confidentiality.

**Unknown or Unforeseeable Risks**

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.

**WILL I BE PAID TO PARTICIPATE IN THE STUDY?**

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 $75 after the first session, $100 after the second session, and $125 after the third session. In all, you can earn $300 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.

You will be asked to provide your social security number in order to receive payment for your participation. Your social security number is required by federal law. It will not be included in any information collected about you for this research. Your social security number will be kept confidential and will only be used in order 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 or for a referral 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.

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

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
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

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

## HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have 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

In general, we will not give you any individual results from the 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 Website will include a summary of the results. You can search this Web site at any time.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

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. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**Dr. Alison Breland; (804) 827-3562 or cstp@vcu.edu**

and/or

**Ms. Barbara Kilgalen**; **(804) 827-3562 or cstp@vcu.edu**

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/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** | |
|---|---|
| _____<br>Adult Participant Name (Printed) | |
| _____<br>Adult Participant's Signature | _____<br>Date |
| _____<br>Name of Person Conducting Consent Discussion (Printed) | |
| _____<br>Signature of Person Conducting Consent Discussion | _____<br>Date |
| _____<br>Principal Investigator Signature (if different from above) | _____<br>Date |