

Title: The Impact of Vaping Ethanol in the Evaluation of Impairment

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: The Impact of Vaping Ethanol in the Evaluation of Impairment

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SPONSOR: National Institutes of Justice

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 purpose of this research study is to find out about ethanol-containing e-cigarettes' impact on ethanol breath tests, field sobriety tests, or other tests of sobriety. Ethanol is a common part of e-cigarette liquids.

What will happen if I participate?

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

1. When you arrive for each visit, we will ask you to wear a mask at all times except when you are using the ECIG we provide.
2. At the in-person screening visit (this visit), we will ask you to answer questions about your health, tobacco use (including e-cigarettes), and alcohol and drug use. Also, at this visit, we will ask to see a form of identification with your date of birth. This is to verify your age.
3. At the in-person screening visit (this visit), we will ask you to provide a urine sample that we will test for drugs (specifically, amphetamine, barbiturates, benzodiazepines, cocaine, THC, methadone, methamphetamine, opiates [which includes

heroin, morphine, oxycodone, oxymorphone, hydrocodone, and hydromorphone], phencyclidine, propoxyphene, and tri-cyclic antidepressants). and for pregnancy. After this analysis, your urine sample will be immediately destroyed).

4. At the in-person screening visit (this visit), we will ask you to provide a breath test where you blow through a tube for levels of carbon monoxide (usually found in cigarettes).
5. At the in-person screening visit and at the beginning of each session visit, we will ask you to take a breath test for levels of alcohol in your body. These tests involve blowing through a tube. If positive at any session visit, you will not be able to participate that day.
6. At the beginning of each session visit, we will ask you to provide another urine sample that we will test for drugs. If positive, you will not be able to participate that day. After this analysis, your urine sample will be immediately destroyed.
7. Visit the Center for the Study of Tobacco Products 4 times for approximately 3-hour study visits, which must be separated by at least 48 hours.
8. Before each visit, abstain from food for at least 2 hours and ethanol for at least 24 hours.
9. Each session will begin with a 90-minute 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 can use your phone, watch a movie, or read.
10. Once study procedures begin, we will ask you to turn off your cell phone for the duration of the session.
11. During each session, we will ask you to respond to several questionnaires to measure how you feel before and after you use an e-cigarette.
12. During each session, we will monitor the ethanol levels in your body several times with two simple tests in which we will ask you to blow through a tube. These ethanol breath tests will be conducted by an off-duty, plain-clothed Richmond Police Department (RPD) or VCU police officer. These police officers will conduct these breath tests because they have specific training on how to administer the tests correctly. These police officers are not acting on behalf of VCU or RPD.
13. Please note that if you belch before this test is conducted, you will need to wait for a few minutes until the test can be administered. This may increase the length of the session.
14. During each session, an off-duty, plain-clothed RPD or VCU police officer will administer a standard field sobriety test. This will involve 1) the officer looking at your eyes, 2) the officer asking you to walk 9 steps and then turn and walk for 9 more steps, 3) the officer asking you to stand on one leg.
15. During each session, an off-duty, plain-clothed RPD or VCU police officer will administer a horizontal and vertical gaze nystagmus test using a device that records video of your

eyes and all audio during recording. This test will involve 1) the officer asking you to rest your head against the recording device and 2) the officer asking you to follow an object with your gaze. This test is brief, 1-2 minutes.

16. In each session, you will receive an e-cigarette loaded with e-liquid that contains either no ethanol or some ethanol (neither will contain any nicotine). For each session, you will not know the concentration of ethanol in the e-liquid. 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 for either one puff, or for 10 puffs. We will tell you when to take each of these puffs. At each of these two times we need you to remain seated in a comfortable chair while you are using the e-cigarette.
17. 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).
18. 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.
19. We will provide you with snacks and juice at the end of each session.

Your participation in this study will last up to 13 hours. Approximately 10-20 individuals may participate in this study.

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. If you do not feel comfortable answering questions on the computer, paper forms are available.

What are the risks and benefits of participating?

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

| Most Common Risks and Discomforts | Benefits to You and Others |
|---|--|
| 1. The e-cigarette liquid that we give you may contain more ethanol than what is in the liquid you usually use, although the liquids we are using are all available on the market. Inform the study staff immediately if you experience any discomfort. | 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 |

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|---|--|
| <ol style="list-style-type: none">2. The effects of inhaling ethanol might include feeling dizzy or lightheaded, delayed reaction time, drowsiness, and nausea.3. In addition, some people who use ecigarettes 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. The seizures may also be related to nicotine exposure.4. 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 Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for 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.5. 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 medical danger. If this occurs, we will immediately replace the electronic cigarette device you are using.6. You may feel uncomfortable interacting with a police officer during administration of the tests. The officers conducting the tests in this study are working off-duty and do not represent VCU or RPD. They have been trained on how to conduct research ethically in this study, and will not have access to any other data in the study, such as the results of your urine drug tests7. You may find the monitoring equipment uncomfortable. | <p>research study may lead to a better understanding of ecigarettes.</p> |
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| <p>8. 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.</p> <p>9. 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.</p> <p>Non-Physical Risks:</p> <p>9. 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.</p> <p>10. The study questionnaires ask personal questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.</p> | |
|---|--|

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.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

This study is not likely to help you. However, it may help the investigators understand how ethanol in e-cigarettes affects tests of sobriety.

WHAT ARE THE COSTS?

There are no costs to participate in this study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will receive \$15 after completing the screening visit (this visit), \$50 after completing the first session, \$65 after completing the second session, \$85 after the third session and \$100 after completing the fourth session. Thus, the total amount you could earn for the entire study is \$315. You may also be reimbursed for parking costs associated with screening and session visits. All payments will be in the form of cash. Total payments within one calendar year that exceed \$600 will require the University to report these payments annually 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 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.

If you leave the study before the final regularly scheduled visit, you may 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 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. 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:

- Representatives of VCU and the VCU Health System involved in the protection of research subjects
- Office of Human Research Protections (OHRP), Dept of Health & Human Services

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

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.

The information you provide will be protected under a federal Privacy Certificate approved by the National Institute of Justice, which prevents identifying information from being accessed by anyone outside of the research team. The Federal law on confidentiality (34 U.S. Code §10231 - Confidentiality of information reclassified from 42 USC 3789g) that applies to this study says that the identifiable data we collect about you can only be used for research purposes, and no other purpose without your consent.

Your confidentiality will only be breached if we learn that someone who is currently under the age of 18 is being abused (child abuse; per VA code §63.2-1509), or if we learn of elder abuse (per VA code §63.2-1606). Please understand that we will need your signature where indicated below acknowledging that confidentiality may be broken in the circumstances described above. If you do not consent to reporting, you may not participate in this study.

If we determine that you are in immediate danger of harming yourself or others, we may report this to authorities without your consent (per VA code §54.1-2400.1). Future criminal conduct may also be reported to authorities.

Project findings and reports prepared for dissemination will not contain information that can reasonably be expected to be identifiable. At the end of the study, a copy of all the data (without any information that could identify you) will be submitted to the National Archive of Criminal Justice Data.

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.

To help us protect your privacy, we have obtained a Privacy Certificate from the National Institute of Justice. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

You should understand that a Privacy Certificate 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.

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

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:

Alison Breland, (804) 827-3562 or abbrelan@vcu.edu and/or

Michelle Peace, (804) 827-8591 or mrpeace@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 | |
|--|-------|
| _____ | |
| Adult Participant Name (Printed) | |
| _____ | |
| Adult Participant's Signature | _____ |
| | Date |
| _____ Name | |
| of Person Conducting Consent Discussion (Printed) | |
| _____ | |
| _____ | _____ |
| of Person Conducting Consent Discussion | Date |
| Signature | |
| _____ | |
| Principal Investigator Signature (if different from above) | _____ |
| | Date |

| Signature Block for Breach of Confidentiality | |
|---|-------|
| By signing below, you acknowledge the circumstances under which confidentiality can be broken. | |
| _____ | |
| Adult Participant Name (Printed) | |
| _____ | |
| Adult Participant's Signature | _____ |
| | Date |
| _____ Name | |
| of Person Conducting Consent Discussion (Printed) | |
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| _____ | _____ |
| Signature of Person Conducting Consent Discussion | Date |