

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: The Impact of Oral Ethanol and Vaped Ethanol in the Evaluation of Impairment

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SPONSOR: National Institute 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 how ethanol (alcohol)-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. 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.
2. At the in-person screening visit (this visit), we will ask you to provide a urine sample that we will test for drugs and for pregnancy.
3. At the in-person screening visit (this visit), we will ask you to take 2-3 practice puffs from an e-cigarette.
4. 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 and a test for carbon monoxide levels in your body. These tests involve blowing through a tube. If positive for alcohol at any session visit, you will not be able to participate that day.
5. At the beginning of each session visit, we will ask you to provide another urine sample that we will test for drugs and pregnancy (if applicable). If positive for any drug, you will not be able to participate that day. We will also ask you for additional urine samples in each session visit. We will store a portion of your urine for later testing.
6. Visit the Center for the Study of Tobacco Products 4 times for approximately 6-hour study visits, which must be separated by at least 48 hours.
7. Before each visit, abstain from food for at least 2 hours and alcohol for at least 24 hours.
8. Each session will begin with a 60-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.
9. During this 60-minute 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, 6 samples per session). 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 less blood than the amount you would give in a single donation 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 you spent complying with the study conditions before the session began (\$15) and also for the time you spend in the laboratory (\$15/ hour).

10. 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).
11. During times when study procedures are ongoing, we will ask you to not use your phone.
12. 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.
13. During each session, we will monitor the ethanol levels in your body several times with simple tests in which we will ask you to blow through a tube. These ethanol breath tests will be conducted by a plain-clothed VCU police officer. 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, a 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. When the officer is administering the eye test, they will use 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 we will ask for samples of oral fluid—this involves placing a swab in your mouth for several minutes.
17. In each session you will receive a beverage that contains either no ethanol or some ethanol. For each session, you will not know the concentration of the ethanol in the liquid. During the session we will ask you to drink this beverage within 20 minutes. In sessions that you receive a beverage with ethanol, the amount you will receive is based on your weight. For example, for a 150 pound person, the amount of ethanol will be similar to 3-4 alcohol-containing beverages.
18. 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). During the session we will ask you to use the electronic cigarette we provide for 10 puffs at two separate timepoints. We will tell you when to take each of these puffs. Each of time we need you to remain seated in a comfortable chair while you are using the e-cigarette.
19. For each session, we will not tell you whether or not the beverage or the e-cigarette contains ethanol. This is called blinding, and it is done so that a fair evaluation of results may be made.
20. 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).
21. 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.
22. We will provide you with snacks and juice at the end of each session.
23. Samples of urine, blood, and oral fluid will be tested for ethanol metabolites and biomarkers of inflammatory response and oxidative stress.
24. Once the study is completed, and your blood samples, oral fluid samples, and urine samples have been analyzed, they will be destroyed.
25. Transportation: for each study session, you must either get a ride to and from the laboratory from a friend/family member, or we can arrange for an Uber ride for you. If we arrange an Uber ride for you, please note that (1) we can only pick you up from your home address and drop you off at your home address, (2) you may need to add the Uber app to a smartphone and (3) Your home address must be within 20 miles of the laboratory.

Your participation in this study will last approximately 25 hours. Approximately 15-20 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
<ol style="list-style-type: none"> 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. 2. The effects of inhaling or drinking ethanol might include feeling dizzy or lightheaded, delayed reaction time, drowsiness, and nausea. 3. 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. 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 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. If you use e-cigarette products, monitor yourself for all of these symptoms. 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 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 or infection. 7. Your heart rate and blood pressure may increase; if either increases above acceptable limits, your participation may stop 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. 11. Drinking ethanol involves risks to a developing embryo or fetus. 12. There are risks associated with leaving the laboratory early following alcohol administration If you choose to terminate 	<p>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.</p>

<p>participation after alcohol administration, you must remain in the lab until your BAC falls below 0.05 g%.</p> <p>Non-Physical Risks:</p> <p>13. 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>14. The study questionnaires ask personal questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.</p>	
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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, other than any fees related to receiving text messages.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will receive \$15 after completing the screening visit (this visit), \$100 after completing the first session, \$125 after completing the second session, \$175 after the third session and \$200 after completing the fourth session. Thus, the total amount you could earn for the entire study is \$615. You may also be reimbursed for parking costs associated with screening 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

If you would like to withdraw your data from the study, you can contact the study investigator, who will work with study staff to remove all of your data. You can do this via phone, e-mail, or in person.

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 participants
- 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. The Department of Justice regulations prohibit any disclosure of identifiable information, except where the researcher learns of intent to commit future criminal conduct.

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 Brelan, (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)

Signature of Person Conducting Consent Discussion

Date

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)

Signature of Person Conducting Consent Discussion

Date