Experimental Study Consent Form
Eastern Virginia Medical School (EVMS) Institutional Review Board

Study Title:	**Effects of Nicotine Salts on Cigarette Smokers**
Name of Investigator:	**Paul T. Harrell**
Sponsor:	**Funding, VCU**
Name of Subject:	

WHY IS THIS STUDY BEING DONE?
You are being asked to participate in a research study involving the collection of information in the forms of questionnaires and real-time assessment of your responding while smoking a cigarette and using electronic nicotine delivery systems ("e-cigarettes"). The purpose of the research project is to enhance our understanding of the effects of nicotine salts in liquids contained in e-cigarettes.

WHY ARE YOU BEING ASKED TO TAKE PART?
You are being asked to participate in this research project because you are a regular cigarette smoker with no other chronic health concerns.
This is a research study. This study includes only people who choose to take part. Please take your time to make your decision and feel free to ask any questions you might have.

WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?
At EVMS about 30 people will take part in this study. We will need you to be in the study for approximately 12.5 hours of your time over 4 non-consecutive days. Besides the initial screening visit, each session will occur no more than 2 days per week and will be separated by at least 48 hours.

WHEN SHOULD YOU NOT TAKE PART?
If you have any of the following conditions, you should not take part in this study:
- Unstable or significant current medical condition
- Recent heart attack or other heart conditions including high blood pressure
- Severe immune systems disorders (uncontrolled HIV/AIDS, unstable multiple sclerosis symptoms)
- Respiratory diseases (exacerbations of asthma or COPD) or liver diseases (cirrhosis)
- Use of oral prednisone or dialysis
- Currently pregnant or breastfeeding

WHAT IS INVOLVED IN THE STUDY?
There are a total of 4 visits planned for this study including an initial screening visit. This initial screening visit will involve a Carbon Monoxide breathalyzer and saliva testing for cotinine, a marker for nicotine use. For women, we will also ask for a urine sample for pregnancy testing. In addition, we will review any prescriptions you may be on. We will next assess heartrate and blood pressure using a finger monitor and blood pressure cuff. You will then be asked to complete surveys about your tobacco use and other information.

For the next 3 sessions, you will be asked to abstain from (don't use) tobacco and nicotine use for 12 hours before coming to the laboratory. We will verify your abstinence using biological testing. If testing indicates you still have high levels of recent exposure to tobacco/nicotine, we will reschedule your session for another day. If testing indicates you have not used tobacco and nicotine recently, you will next begin a 1-hour waiting period in the

laboratory. Heart rate and blood pressure will be measured continuously using a finger monitor and blood pressure cuff.

You will then complete a set of surveys, followed by consumption of a tobacco product. The tobacco product will be either a cigarette of the brand you usually use that the research team will provide to you, an "e-cigarette" with 18 milligrams (mg) of nicotine salt (protonated nicotine), or an "e-cigarette" with 18 mg of regular (unprotonated) nicotine. The tobacco product you consume at each session will be randomly assigned (similar to throwing a die). You will use the assigned tobacco product twice at each session. The first time you use the product we will tell you when to puff. The second time you use the product you will be able to use as much or as little as you like for a period of 90 minutes. Before and after each session, you will be asked to complete surveys about how you are feeling and what you think of the tobacco product. Your tobacco product use sessions will be videorecorded.

WHAT ARE THE RISKS OF THE STUDY?

Twelve hours without tobacco may cause mild discomfort and nicotine abstinence symptoms, but is not medically dangerous. Symptoms may include: irritability, anxiety and restlessness, excessive hunger, difficulty concentrating, and sleep disturbance.

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.

In many 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, and the Centers for Disease Control and Prevention has advised people to stop vaping. In some cases symptoms of mild to moderate gastrointestinal illness such as vomiting, diarrhea, or fevers or fatigue have been reported. If you use e-cigarette products, monitor yourself for symptoms (e.g., cough, shortness of breath, chest pain)] and promptly seek medical attention if you have concerns about your health.

A risk associated with allowing your data to be saved is the release of personal information from your study record. We will strive to protect your records so that your personal information (like name, address, social security number and phone number) will remain private.

There also may be other risks that are unknown and we cannot predict.

For Women: Reproductive risks: Because the tobacco products used in this study can affect an unborn baby, you should not become pregnant while on this study. You should not be in this study if you are currently breastfeeding your baby. Counseling and more information about preventing pregnancy is available if you are interested. Acceptable methods of birth control for women include oral contraceptive, IUD, diaphragm, and condom with spermicide.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. There is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other cigarette smokers in the future.

WHAT ABOUT CONFIDENTIALITY?

All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be disclosed if required by law.

You have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.

Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. Reviewers may include, for example, an Eastern Virginia Medical School Institutional Review Board.

Information learned from this research may be used in reports, presentations and publications. None of these will personally identify you.

FDA Clinical Trial Registration

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 Web site will include a summary of the results. You can search this Web site at any time.

What will Participation in the Study Cost or Pay?

If you complete all 4 visits, you will be reimbursed in the amount of $300.00 total for your participation. After completing the initial screening visit, you will be paid for the following 3 sessions. You will receive $75.00 after completing the first session, $100.00 after completing the second session, and $125.00 after completing the third session, resulting in a total payment of $300.00. There are no costs to you associated with taking part in this study

If a session must be discontinued for reasons beyond your control, you will be entitled to payment for time spent complying with study conditions before the session began ($15) and any time spent in the laboratory ($15/hour).

WHAT IF YOU GET INJURED?

In the event of injury resulting from this research study, Eastern Virginia Medical School (EVMS) provides no financial compensation plan or free medical care.

WHAT ABOUT THE COLLECTION OF TISSUE/SPECIMENS?

You are in a study where urine (for women) are collected as part of the research study. After all of the required tests are finished, the specimen will be discarded. The specimens will be destroyed by the end of the study.

What are your Rights as a Participant?

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time. If you do leave the study, discuss it with the investigator who will help you do so in the safest way. If you leave, the study it will not result in any penalty or loss of benefits to you.

The investigator may decide to take you off this study if you cancel your approval, or are unable to maintain tobacco/nicotine abstinence (fail bioverification checks more than once).

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have any questions pertaining to this research or believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Paul Harrell at (757) 446-6047 and/or by e-mail at harrelpt@evms.edu. You may also contact Ms. Betsy Conner, Director of Eastern Virginia Medical School Human Subjects' Protection Program & IRB Office, at (757) 446-5854. If you have any questions pertaining to your rights as a research subject, you may contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

SIGNATURE			
You will get a copy of this signed form. You may also request information from the investigator. By signing your name on the line below, you agree to take part in this study.			
_____ Signature of Participant	_____ Typed or Printed Name	_____ Relationship to Subject	___/___/___ MM/ DD/ YY

STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE	
I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.	
_____ Signature of Investigator or Approved Designee	___/___/___ MM/ DD/ YY

IRB APPROVAL
DATE 02-21-20
EXPIRES
DATE 12-16-20
IRB #19-01-FB-0009