RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Effects of an Oral Nicotine Product in Smokeless Tobacco Users

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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 study doctor 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 how three different nicotine pouches and your own brand of smokeless tobacco affect blood nicotine levels and how you feel.

The results of this study will be used to help us better understand how nicotine pouches affect blood nicotine levels and how you feel.

What will happen if I participate?

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

1. Visit the Center for the Study of Tobacco Products 4 times for approximately 4-hour study visits, which must be separated by at least 36 hours, and which will not occur more than two times per week.
2. Before each visit, abstain from **all** tobacco products (smokeless tobacco, ecigarettes/vapes, cigarettes, cigars, and hookah/waterpipe) for at least 12 hours. In

addition, the use of any nicotine-containing products (like 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 ask you to abstain from caffeinated beverages for 1 hour before each session.
4. During the study sessions, we will ask you limit your cell phone use and not use it at all when you are completing study tasks.
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 can use your phone and/or we will provide you with a movie to watch or a 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, 5 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 blood 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 a nicotine pouch or smokeless tobacco.
8. During each session, we will measure the carbon monoxide levels in your breath with a simple test in which we will ask you to blow through a tube.
9. In each session, you will receive a nicotine pouch or smokeless tobacco that contains nicotine. For each session, you will not know the concentration of nicotine in the nicotine pouch, but you will know the concentration and brand of the smokeless tobacco (it will be your usual brand). This is called blinding, and it is done so that a fair evaluation of results may be made. During each session we will ask you to use the nicotine pouch or smokeless tobacco that we provide two separate times. At each of these two times we need you to remain seated in a comfortable chair while you are using the nicotine pouch or smokeless tobacco.

10. 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). We will also measure the carbon monoxide levels in your breath with a simple breath test in which we will ask you to blow through a tube. At this visit, we will ask to see a form of identification with your date of birth to verify your age.

Your participation in this study will last up to 18 hours. Approximately 32 individuals will complete 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. You may experience some discomfort during abstinence from tobacco and nicotine before the session or while using the nicotine pouch 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. 2. The nicotine pouch that we give you may contain more nicotine than you usually use, although some smokeless tobacco users report using tobacco at these nicotine concentrations. Inform the study staff immediately if you experience any discomfort. 3. Side effects from tobacco/nicotine abstinence can include irritability, anxiety and restlessness, excessive hunger,	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 nicotine pouches.

difficulty concentrating, and sleep disturbance. These are common abstinence symptoms in tobacco users. Though uncomfortable, these feelings are not medically dangerous. 4. 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. 5. You may experience a tingling or burning sensation in your mouth when using the pouch we provide. You may find this unexpected and/or unpleasant. This experience has been reported by smokeless tobacco users, and does not appear to present any known medical danger. 6. Your heart rate and blood pressure may increase; if either increases above acceptable limits, your participation may be stopped for your safety. 7. You may find the monitoring equipment uncomfortable. 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 participation in the study. 9. The use of nicotine pouches involves risks that are currently unknown or unforeseeable. Using nicotine pouches may involve risks to a developing embryo or fetus that are currently unknown.	

Non-Physical Risks 10. 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. 11. 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. However, if we find something of medical importance to you, we will inform you (such as evidence of high blood pressure or a positive pregnancy test).

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 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 nicotine pouches.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $15 for completing the initial screening visit. You will be paid for the time that you are not using tobacco prior to each session and for your time in laboratory: you will receive $75 after the first session, $100 after the second, $150 after the third, and $200 after the fourth session. In all, you can earn $540 for completing this study. All payments will be made in cash.

In addition, if you complete the screening visit, we will give you 5 cards that have our lab information and a number/letter combination on them. The numbers/letters on the cards are linked (by us) to your name/email address. You can give these cards to friends or family members who might want to participate in any of our ongoing lab studies that involve in-person screening visits. If someone you give a card to completes the initial survey via cstpstudies.vcu.edu, appears eligible to participate in one our laboratory studies, attends the in-person screening visit, and brings a card back to us, we will send you an additional $20 per returned card, paid via Amazon gift code e-mailed to you. We will not tell you who brought us the card. The cards expire after one year.

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 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 study doctor without your consent. The reasons might include:

- the study doctor 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 withdraw from the study, data that has already been collected about you will remain part of the study database and may not be removed.

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

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.

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. 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.

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:

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, 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

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