RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Effects of E-cigarette Flavors Among African American Menthol Smokers (RVA-Flavors)

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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 that is being conducted by VCU's Drs. Caroline Cobb and Andrew Barnes. **It is important that you carefully think about if 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.**

Your participation is voluntary. You may decide to not 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.

A BRIEF OVERVIEW OF THE STUDY AND KEY INFORMATION

The purpose of the study is to understand how varying the flavors ("Tobacco," "Menthol," and "Unflavored") available for an *electronic cigarette or (e-cigarette) product* impacts measures of tobacco use behavior, biological measures of cigarette and e-cigarette exposure, and the likelihood someone might use/abuse these products.

Most e-cigarettes contain nicotine but likely have fewer toxic chemicals compared to cigarettes. For smokers, e-cigarettes could be a less harmful alternative if used as a complete substitute for all cigarettes and other smoked tobacco products. E-cigarettes are not currently approved by the FDA as a quit smoking aid.

This study focuses on Black/African American menthol cigarette smokers because this group of individuals has historically been unfairly targeted by the tobacco industry and harmed by tobacco products. In addition, limited research has been conducted with African Americans to identify possible policies to reduce these harms. The results of this study will help us to better understand the effects of e-cigarette product flavors and their potential to reduce harm among African American menthol smokers.

A summary of study activities is included in Table 1 below and more detail on each of these activities is provided on page 4 of this consent form.

Table 1. Overview and Timeline of Study Activities					
Enrollment	In-person screening and consent	Week 0 (baseline week & randomization visit)	Week 1, 2, 4, and 5 (remote visits)	Weeks 3 and 6 (in-person visits)	30-day follow-up survey
• Assess eligibility online or by phone. • Schedule an in-person visit to confirm eligibility and complete baseline measures	Come to the study site to: • Review and sign a consent form • Confirm eligibility by answering questions • Complete (a) urine test(s) to confirm that you are not pregnant and you are a smoker. • Complete a breath test to confirm you are a smoker • Complete baseline survey • Present a photo ID for age verification • If you opt-in to the VYTP project, complete measures related to racial discrimination and socialization	• Respond to daily surveys <u>At the end of baseline week (Week 0) come to the study site to:</u> • Perform breath tests and provide a urine sample. • Complete an online survey • Receive study e-cigarette products	• Respond to daily surveys • Complete an online survey at the end of each week <u>At the end of Week 2 and 5:</u> • Complete a phone call that will be audio-recorded so study staff can ask you additional questions about your experiences with the e-cigarette products.	• Respond to daily surveys You can come to the study site or we can come to your home to: • Perform breath tests and provide a urine sample • Complete an online survey at the end of each week • Receive and/or return study e-cigarette products	• Complete an online survey

PARTICIPATION IN THE VIRGINIA YOUTH TOBACCO PROJECTS (VYTP) PROJECT

The VYTP part of the study focuses on the impact of race, both positive and negative, on tobacco use. More specifically, this project aims to understand how race-related factors during adolescence impact tobacco use in adulthood. You are eligible to participate in this part of the study if you are aged 21 or older. If you are eligible, you have the opportunity to opt-in to this portion of the study, or you may choose to not complete this part of the project.

WHAT ALTERNATIVES ARE AVAILABLE?

This is not a therapeutic study. You have the alternative not to participate.

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

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

Most Common Risks and Discomforts

Physical Risks:

1. Frustration - You may experience mild frustration while completing some of the study-related questionnaires.

2. Nicotine-related side effects - You may experience side effects from products that contain nicotine such as acute increases in heart rate and blood pressure, sweating, lightheadedness, dizziness, nausea, and nervousness. These side effects are unlikely to arise in individuals who use cigarettes regularly.
3. The Centers for Disease Control and Prevention advises that e-cigarette, or vaping products are unsafe for youths, young adults, or people who are pregnant. Adults who do not currently use tobacco products should not start using e-cigarette/vaping products. If you use e-cigarette products, monitor yourself for the below symptoms and promptly seek medical attention if you have concerns about your health.
    a. 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.
    b. 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.
    c. In some cases, e-cigarette use has been associated with symptoms of mild to moderate gastrointestinal illness such as nausea, abdominal pain, vomiting, diarrhea, fevers, or fatigue.
4. The use of e-cigarettes may include other side effects/risks such as a sore or scratchy throat and headache.
5. E-cigarette companies have to apply to the Food and Drug Administration (FDA) and be approved for sale in U.S. markets. In June 2022, the FDA denied the marketing application from JUUL, the manufacturer of the e-cigarettes used in this study. The FDA determined that JUUL did not provide enough evidence about the toxicity of its e-cigarette device and pods in its application. However, the FDA has not received clinical information to suggest an immediate hazard associated with the use of JUUL devices or JUUL pods. The FDA decision to ban the sale of JUUL is not final yet due to ongoing legal disputes. When and if the FDA's decision to ban JUUL is final, it will be illegal to sell JUUL products. However, it will still be legal for researchers to study these products and for participants to use them.
6. Lung function testing (Spirometry) – Risks associated with spirometry may include shortness of breath, dizziness, headache, and on rare occasions fainting while doing the breathing test. Participants with medical conditions that may place them at increased risk are being excluded.
7. Nicotine withdrawal symptoms – Some participants may experience nicotine withdrawal symptoms when they reduce their own brand cigarette consumption. Common withdrawal symptoms are irritability, anxiety, depressed mood, increased appetite, fatigue, or difficulty concentrating. These will be monitored by the researchers.
8. New pregnancy or want to become pregnant – Nicotine, either from cigarettes or e-cigarettes, is known to be harmful to the developing human fetus. Those who are intending to become pregnant, currently pregnant, or are nursing a child may not participate in this research study. We will provide you a packet containing information about contraception resources at the screening visit to help prevent pregnancy during the study. If at any point during the research you believe there is

any possibility that you may be pregnant, please notify the research staff immediately.

9. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that may make you change your mind about participating in the study.

Non-physical Risks

1. Privacy - 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.
2. Sensitive questions - The study questionnaires ask personal questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable except those needed to confirm your eligibility.

BENEFITS TO YOU AND OTHERS

1. There may be a direct benefit to you in terms of decreased use of conventional cigarettes that are known to be lethal over the long-term. However, no medical benefit can be guaranteed.
2. Your participation will help us in the future as we try to better understand e-cigarette product effects and the availability of different flavors among African American menthol smokers. Your participation may also benefit others by helping to provide the scientific information needed to regulate tobacco products equitably.
3. In general, we will not give you any of your individual results from this study.

ADDITIONAL DETAILS ABOUT STUDY ACTIVITIES AND KEY INFORMATION

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

1. **To enroll in the study**, you will be asked to provide your contact information, medical history, and tobacco/alcohol/drug use history through an online or telephone survey. If your responses indicate that you are eligible for the study, we will schedule an in-person visit at our lab to confirm your identity/contact information and review study related procedures. Please note, you may skip any survey questions administered (at any point in the study) except for those needed during the baseline survey to determine your eligibility.
2. **If your initial responses indicate you fulfill the eligibility criteria**, we will ask you to come into our study site (our lab located near VCU's Medical Campus) to complete a screening session. At the screening session, we will ask you to fill out some forms about yourself, including information on your medical history, tobacco/alcohol/drug use, and perceptions of tobacco products. At this screening session, we will also collect and test your urine sample to ensure that you qualify to participate in the study. Urine testing will include a test for nicotine to confirm you use tobacco products and a pregnancy test, as pregnant people are not eligible to participate in this study. At the screening visit we will also ask you to complete a breath test to confirm you are a smoker. We will also ask to see a form of identification with your date of birth to verify your age.

a. If you are eligible for the VYTP project and opt-in, you will complete a series of measures related to adolescent racial discrimination and socialization that will take an additional 25 minutes.

3. **If the urine and breath tests and your answers to our questions indicate you fulfill the eligibility criteria**, you will be asked to monitor how many cigarettes you smoke each day for the next week (7 days). You will also be asked to avoid using any tobacco products other than your menthol cigarettes during this week. This first week of the study is called the "baseline week" or Week 0. You will report this information using a daily online survey that is sent via text message.
4. **If you successfully complete the baseline week**, we will contact you to schedule a time for you to complete the randomization visit and receive your randomly assigned *e-cigarette* flavor condition at our study site. This means your condition assignment will be determined purely by chance, like flipping a coin. You will have an equal chance to receive the e-cigarette products in:

Tobacco flavor only

OR

Tobacco and Menthol flavor

OR

Unflavored only

5. At the **randomization visit** you will:
    a. Receive your assigned e-cigarette products, have training on how to use the e-cigarette products, and take 4 practice puffs of each flavor assigned to you.
    b. Complete two breath tests that involve exhaling into a disposable mouthpiece for several seconds. One test will measure your exposure to cigarettes (just like you will be asked to do at screening) and the second one will measure how well your lungs function.
    c. Provide a urine sample to measure exposure to cigarettes and e-cigarettes.
6. **You will then be asked to use the provided e-cigarette product to replace some or all of your own brand menthol cigarettes and to avoid using any other nicotine/tobacco products for the next six weeks**.
7. Over the next six weeks after receipt of the e-cigarette product (Weeks 1 through 6), you will be asked to:
    a. Continue to respond to daily online surveys about your tobacco use.
    b. Complete a weekly survey about your tobacco use, experiences with your provided e-cigarette, and other related measures. The first weekly survey will be sent to you about 7 days after randomization. This survey will vary by week but will always include questions about any changes in your health and/or current medications. Staff will follow-up regarding any changes in-person or via phone (if completed remotely). Week 3 and 6 surveys will include hypothetical purchase tasks asking how much you

would pay to use your own brand menthol cigarettes and the e-cigarettes provided to you.

c. Complete a semi-structured interview with study staff during Week 2 and 5. Here you will be asked to discuss your e-cigarette use over the last week or two, how it's going, and what you do and don't like about your provided e-cigarettes via a phone call with study staff. Both these discussions will be audio recorded so we can accurately capture what you tell us. Please note, audio-recordings will be maintained in locked file cabinets and/or secure electronic location until they are transcribed and then the audio-recordings will be destroyed. All names/direct identifiers will be removed from the audio-recording transcriptions.
d. During Week 3 and Week 6 we will ask you to return to the study site or we can visit your home to perform the visit. During these visits, we will ask you to:
    i. Complete the same two breath tests you did earlier in the study, if in-person at the BHRL lab **OR** complete the same breath test you did earlier in the study if in-person at your home.
    ii. Provide a urine sample.
    iii. Return your used and unused e-cigarette pods for us to count.
e. We will provide you with a container to store your e-cigarette products throughout the study. After you finish or empty one of the e-cigarette pods, we will ask that you save these used pods and bring them back to us on Week 3 and 6 (in addition to any unused pods). Also, on Week 3 we will provide additional e-cigarette pods as needed.

8. About 30 days after you finish the study, we will ask you to complete an additional online survey about your tobacco use and how you feel.

Your participation in this study will last approximately 11-12 weeks in total. Procedures will be completed in-person and via remote methods (online/phone).

In-person visits last about 60-120 minutes. **The initial screening/baseline visit and end of Week 0 visit will occur at the study site. Participants can attend Week 3 and Week 6 visit at the study site OR at their home (up to participant preference).**

For at home visits, study staff will remain outside and provide/receive study-related materials at the building door/main entrance. For at home visits, participants will receive an online survey containing weekly measures.

Other remote visits involve completion of a weekly online survey. These visits (and any follow-up phone calls) will take between 30-60 minutes with the exception of Week 2 and Week 5 (optional 15-minute audio-recorded interview).

The online follow-up survey 30 days after Week 6 will take between 30-60 minutes.

The daily surveys will take less than 3 minutes to complete each day over seven weeks.

About 210 individuals will participate in this study.

This study will **not** use your urine samples to sequence all or any part of your DNA or look at anything except for the measures described above.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

At a minimum, you will be paid $20 for completing the survey at the in-person screening to determine your eligibility to participate. If your answers to this survey meet our criteria, we will also ask you to complete breath and urine samples for an additional $20.

If you are enrolled following the in-person screening, completion of daily surveys are worth $1 a day with a $10 bonus for completing 7 days/surveys in a row for a total possible compensation of $119 (over 7 weeks). If you are eligible and choose to participate, you will be asked to complete a remote visit on Weeks 1, 2, 4, and 5 ($20 for survey and other measures at each visit). For the in-person visits, you will be paid $40 for the survey and other measures + $20 for breath and urine samples ($60 in total at each visit). During Weeks 2 and 5 you will be paid an additional $20 per visit for completing the interview. You will also be paid $30 at the in-person Week 3 and Week 6 visits for returning your used and unused e-cigarette pods in the containers we will provide to you. For the online follow-up survey you will be paid $20. You can receive a $75 bonus for completing all study visits from Week 0 through Week 6.

If you complete all phone calls and comply with answering daily surveys and in-person visits, you can receive up to $654 (varies based on the number of daily surveys completed, whether you bring back your used study products, and whether you complete all study activities). Compensation for all in-person visits (screening and sessions) and daily surveys and phone calls will be paid in cash. You will receive payments for study-related activities completed to date at the in-person visits or you can schedule a time to receive your current payments in-between these visits.

For the in-person screen/visits you will be reimbursed for parking/travel expenses ($10).

If you opt-in to participate in the VYTP project, you will be compensated an additional $40 at your screening/baseline visit.

How you are paid for completing each activity in this study

	Screening /Baseline	Randomization	Weekly study visits						30-day follow-up
Study Week	*-1*	*0*	*1*	*2*	*3*	*4*	*5*	*6*	*~10*
Approximate length visit (min)	*60-120*	*60-120*	*<60*	*<60*	*60-120*	*<60*	*<60*	*60-120*	*<60*
Survey and other measures	$20	$40	$20	$20	$40	$20	$20	$40	$20
Interview	-	-	-	$20	-	-	$20	-	-
Breath and urine samples	$20	$20	-	-	$20	-	-	$20	-
Returning used/unused e-cigarette pods	-	-	-	-	$30	-	-	$30	-
Parking/travel	$10	$10	-	-	$10	-	-	$10	-
Daily text surveys ($1/day+$10 compliance)	-	$17	$17	$17	$17	$17	$17	$17	-
Visit attendance bonus	-	-	-	-	-	-	-	$75	-

VYTP Project Participation	*$40*	-	-	-	-	-	-	-	-
Maximum compensation/week	$50-90	$87	$37	$57	$117	$37	$57	$192	$20

Participants who enroll but later become ineligible or withdraw for any reason can schedule a time to pick up their compensation earned to date at our study site or have us email an Amazon gift card to them.

In addition, if you are eligible for the study, 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/e-mail address. You can give these cards to friends or family members who might want to participate in this study. If someone you give a card to attends an in-person screening visit with the card, you can receive an additional $20 per returned card, paid in cash or Amazon gift card (email). We will not tell you who brought us the card. The referral cards expire after one year.

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. 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 the main study site (804-828-1867) and/or your study doctor (Dr. Thokozeni Lipato; thokozeni.lipato@vcuhealth.org) 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 and to report discomfort and side effects to study staff

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time without punishment or negative consequences. 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 assessment, you will be able to keep any money that you have 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 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 the future, identifiers might be removed from the information you provide in this study (including results of the urine analyses described above), and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent. There are no plans to share any money or profits with you if the use of your information results in inventions or discoveries that have commercial value.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality 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.

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

If you have any questions, complaints, or concerns about your participation in this research, the best persons to contact are:

Dr. Caroline Cobb at 804-827-3562 / email: cobbco@vcu.edu or

Dr. Andrew Barnes at 804-827-4361 / email: andrew.barnes@vcuhealth.org

The medically responsible investigator is Dr. Thokozeni Lipato
thokozeni.lipato@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Phone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. 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 have the opportunity to keep a copy of the consent form for my records.

_____	
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

VYTP Project Opt-in

I have been provided with information about the VYTP project. I understand that my participation is voluntary, and I can choose to opt-out of this part of the study. All of the questions that I wish to raise concerning this part of 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 portion of the research study.

_____	
Adult Participant Name (Printed)	
_____	_____
Adult Participant's Signature	Date