**VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY**

# Consent to Take Part in a Research Study

**22-432 Effects of narratives on demand for low and high ventilated cigarettes and substitution for alternative products.**

**NCT: NCT05487625**

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# Consent to Take Part in a Research Study

**Title of research study:** Understanding use of high- and low-ventilated cigarettes and alternative tobacco products (IRB# 22-432)

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**Key Information:** The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form. This study will allow us to look at how people use and purchase different tobacco/nicotine products, such as high- and low-ventilated cigarettes, nicotine vaping products, chewing tobacco, nicotine gum, nicotine lozenges, and snus. You will be required to come to this location approximately two times. You will complete questionnaires on a computer, have the opportunity to sample a range of tobacco products, and purchase tobacco products in an experimental online store. At the end of the study, you will complete an additional interview over the phone.

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are at least 21 years old and smoke high-ventilated cigarettes daily.

## What should I know about being in a research study?

- Someone will explain this research study to you
- Whether or not you take part is up to you
- You can choose not to take part
- You can agree to take part and later change your mind
- Your decision will not be held against you
- You can ask all the questions you want before you decide

## Why is this research being done?

This study will allow us to examine effects of messages about tobacco products and cigarette price on purchasing of cigarettes and other tobacco products under different scenarios. Your participation

in this study will also help us learn more about how people purchase and use certain tobacco products, which may help us understand harms associated with tobacco use.

## How long will the research last and what will I need to do?

We expect that your participation in this research study will last approximately two weeks. You will be asked to complete approximately two visits to the Addiction Recovery Research Center (ARRC) at the Fralin Biomedical Research Institute (FBRI) or another designated site (including today's session). Each session will last approximately one to two hours. You may be asked to complete questionnaires and computerized tasks that will measure some of your preferences and abilities, and you will be asked to make real purchases of tobacco products under different situations. At the end of the study, you will complete an interview over the phone that will last approximately 30 minutes.

More detailed information about the study procedures can be found under, **"What happens if I say yes, I want to be in this research?"**

## Is there any way being in this study could be bad for me?

Risks are no more than would be expected after using tobacco products. For example: there is a risk that you may become nauseous or dizzy when sampling products that you are not used to using.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)".**

## Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, the current study may help identify effective methods of assessing the use of tobacco products, which may help the health of people in the future.

## What happens if I do not want to be in this research?

Participation in research is completely up to you. You can decide to participate or not to participate. You are free to decline participation in this study or withdraw from it at any time without any penalty or loss of benefits to which you are entitled. If you are a Virginia Tech student, you may withdraw from the study or choose not to participate without affecting your academic standing (i.e., your student status and evaluations will not be affected). If you are a Virginia Tech employee, you may withdraw from the study or choose not to participate without affecting your employment status.

The alternative to participating in this study is not participating.

**Detailed Information:** The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ARRC, by calling (540) 315-0205, or emailing arrc@vtc.vt.edu.

This research has been reviewed and approved by the Virginia Tech Institutional Review Board (IRB). You may communicate with them at 540-231-3732 or irb@vt.edu if:

- You have questions about your rights as a research subject
- Your questions, concerns, or complaints are not being answered by the research team
- You cannot reach the research team
- You want to talk to someone besides the research team to provide feedback about this research

## How many people will be studied?

We plan to enroll about 90 people in this research study.

## What happens if I say, yes, I want to be in this research?

To make sure you are eligible to take part in this study, you will be asked to provide a breath sample to measure recent nicotine use and smoking. If you are a woman of childbearing age, you will be asked to provide a urine sample for a pregnancy test. You will not take part in this study if you are pregnant.

At Session 1, you will be asked to provide some basic information about yourself as well as your tobacco use. You will complete a number of behavioral tasks to assess decision making preferences. At the end of the session, you will be given samples of high- and low ventilated cigarettes, and other tobacco products to try and use outside of the lab so that you may familiarize yourself with their effects. On the following days after Session 1, you will receive text messages asking to report on your cigarette and other tobacco/nicotine products consumption.

At Session 2, you will be assigned to one of three groups that may include messages about tobacco products. The group you get will be chosen by chance, like flipping a coin. Then, you will be given a real amount of money (an "account balance") that you can use to purchase tobacco products, including cigarettes as well as other nicotine/tobacco products, for 7 days. Across different purchasing trials, the price of tobacco products will vary. At the end of the session, you will randomly draw an individual purchasing trial and you will receive all the products you purchased at that trial to use over the next 7 days. You may keep any remaining account balance not spent on tobacco products from the randomly drawn purchasing trial. During the following 7 days, you will be asked to use only the tobacco products you received during the study. At this session, you will also be asked to complete some assessments about your use of nicotine/tobacco products.

At Session 3, you will complete an interview over the phone about tobacco use and related questions.

## What are my responsibilities if I take part in this research?

If you take part in this research, you will be asked to:

- Provide breath and urine samples (if requested) to test for recent nicotine use and smoking.
- Provide a urine sample to test for pregnancy, if applicable.
- Complete questionnaires about tobacco use.
- Complete behavioral tasks to measure your preferences.
- During the purchasing portion of the study, purchase/use only the study-provided nicotine/tobacco products purchased during the lab session.
- Return any products you were provided with.
- Notify the researchers if you cannot attend a scheduled session.
- Notify the researchers if you are experiencing any discomfort or desire to discontinue participation from this study.
- Let the researchers know of any comments, questions or concerns regarding participation in this study.

## What happens if I say yes, but I change my mind later?

You can leave the research at any time, for any reason, and it will not be held against you. You are free not to answer any questions or not respond to what is being asked of you without penalty. There are no "right" or "wrong" answers. We want you to answer the questions honestly and thoughtfully.

Should you withdraw or otherwise discontinue participation, you will be compensated for the portion of the study completed in accordance with the compensation scheme described below.

Please note that there may be circumstances under which the investigator may determine that a participant should not continue in the study.

If you stop being in the research study, we may analyze any collected data unless you specifically request otherwise. If you would like not to have your data included you can call (540) 315-0205, or email arrc@vtc.vt.edu asking your data to be removed.

## Is there any way being in this study could be bad for me? (Detailed risks)

There will be no direct costs for your participation, although there are risks. One risk is possible embarrassment. This may result from answering questions that you consider sensitive. Some of our questions will ask for information about medical and psychiatric conditions and/or nicotine/tobacco use. You may also become bored or frustrated during the research sessions.

In addition, loss of confidentiality is another potential risk of participation. We will make every effort to protect your confidentiality should you participate in this study.

This study includes the risks of potential nicotine withdrawal (e.g., dizziness, headache, irritability, sleepiness, decreased alertness, difficulty concentrating, impatience, sleeplessness, and increased eating). You may also not enjoy sampling the high-and low-ventilated cigarettes or other study products during the sampling period. You may also experience some minor mouth, throat or sinus irritation.

Additionally, because the present experiment will allow that you smoke cigarettes and use other nicotine/tobacco products, you might experience adverse effects associated with the use of nicotine products (e.g., nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat).

The use of nicotine products is known to have bad effects on a fetus. You may withdraw your participation if you are attempting to get pregnant through the course of this study.

Due to the investigative nature of this study, there may be other risks that are currently unknown. We will tell you about any new information that might affect your health, welfare, or choice to stay in the research.

If any problems occur during the course of the study and you are concerned, please contact us at (540) 315-0205 and we will determine whether you should continue in this study. You may wish to stop using the available product(s) until we have made this determination. If necessary, referrals will be provided. Any expenses accrued for seeking or receiving treatment will be your responsibility and not that of the research project, research team, or Virginia Tech.

If you have other questions, concerns, or complaints concerning the study, please contact Dr. Warren K. Bickel, the Principal Investigator at 540-526-2015 (administrative office).

## What happens to the information collected for the research?

We will make every effort to limit the use and disclosure of your personal information only to people who have a need to review this information. We cannot promise complete confidentiality.

We have received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

We will act in accordance with the guidelines for the protection of human research participants issued by the Institutional Review Board (IRB) and Office of Research Compliance (ORC). Your identity on records relevant to this study will not be made public. Any publications resulting from this research will not mention your name or any other personally identifying information.

It is possible that the IRB, the ORC, the Human Research Protection Program, and other authorized representatives of Virginia Tech may inspect and copy your information. The IRB is responsible for the oversight of the protection of human subjects involved in research. The sponsor (the National Institutes of Health/National Cancer Institute), the US Food and Drug Administration, US Department of Health and Human Services, the Fralin Biomedical Research Institute (FBRI) or their

appointed designees may as well be granted direct access to your original research records for verification of data.

If your record is used or distributed for government purposes, this will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law enforcement responsibilities of the agencies.

We may share information that would identify you as a participant in the research project under circumstances involving child or elder abuse or intent to hurt yourself or others.

It may also be necessary to share your identity in order to arrange your compensation for participation. However, we will only share the minimum personal information required to arrange compensation and this information will never include anything related to cigarette use or other study data.

If identifiers are removed from your private information that is collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

A description of this clinical trial 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.

The results of this research study may be presented in summary form at conferences, in presentation, reports, academic papers, and as part of a thesis/dissertation.

## Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include pregnancy, current unstable medical illness, unmanaged psychiatric or neurological disorder, violation of research center policies or failure to attend scheduled sessions or to complete any of the study procedures. We will also stop your participation if your answers or performance suggest that it is not safe and appropriate for you to continue in the study.

## What else do I need to know?

This research is being funded by the National Institutes of Health/National Cancer Institute.

If you agree to take part in this research study, you will receive the following compensation for participating:

Session 1 (up to $40)
- $15 for completion of the consent
- $25 for completion of the assessment session

Session 2 (up to $50)
- $5 for answering text messages
- $20 for product sampling
- $25 for completion of the Experimental Tobacco Marketplace session

Session 3 (up to $35)

$10 for the follow-up phone call
$25 bonus for completing the study

In addition to these amounts, you will also receive money in your study account balance to use in Session 2. You may also receive additional compensation for your travel time, e.g. $11.00 per hour, consistent with Virginia minimum wage.

If you receive compensation greater than $600.00 for studies within a calendar year, the amount received will be reported to the IRS and you will receive an IRS 1099 Form. We will collect social security numbers and retain them for IRS and auditing purposes.

To allow for payments that are both convenient and rapidly available, you will be proved with a prepaid card through Greenphire ClinCard. This is an FDIC-insured payment provider that specializes in research compensation. The card can be used anywhere that accepts MasterCard. You will receive the card at the beginning of the study. Compensation will be added at the end of each session and will be immediately available.

We will not offer to share your individual test results with you.

## Future Research Opportunities

If you would like to be contacted regarding future opportunities for research participation, please initial next to your choice below.

_____ Yes, please contact me regarding future research opportunities.
_____ No, please DO NOT contact me regarding future research opportunities

## Statement of Consent

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

## Signature Block for Capable Adult

Your signature documents your permission to take part in this research. We will provide you with a signed copy of this form for your records.

Signature of subject | Date

## Consent to Take Part in a Research Study

| | |
|---|---|
| Printed name of subject | |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |