Promotion factors and mitigation strategies leading to illegal tobacco purchases

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VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study #IRB 23-825

Title of research study: Decision-making and cigarette purchasing patterns: Study 2A

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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 conventional cigarettes, very-low nicotine cigarettes, nicotine vaping products, nicotine pouches, chewing tobacco, nicotine gum, nicotine lozenges, nicotine patches, and snus. You will be required to come to this location approximately 3 times and complete either an additional in-person visit or receive a phone call. 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.

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

We invite you to take part in this research study because you are at least 21 years old, smoke cigarettes daily or smoke cigarettes and use nicotine vaping products regularly.

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 different policy strategies on purchasing cigarettes, and other tobacco products under different scenarios, including an illegal marketplace where purchases may be fined. 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 the harms associated with tobacco use and purchasing behaviors under different situations.

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 three weeks. You will be asked to complete three in-person visits to FBRI or another designated site (including today's session) and complete either an additional in-person visit or a interview via phone. This session will last approximately one hour and the next two sessions will last approximately 30 minutes. The additional in-person or phone call session should take approximately 30 minutes. During the experiment, you may be asked to complete questionnaires and computerized tasks that will measure some of your preferences, and make real purchases of tobacco products under different situations.

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 for taking part in this research. We cannot promise any benefits to others for taking part in this research. However, the current study may help identify effective methods of assessing the use of tobacco products, which may help improve healthy decision-making of people in the future.

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

Participation in this research is completely up to you. You can decide whether to participate or not. You are free to decline participation in this study or withdraw from it at any time without any negative consequences 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 the Addiction Recovery Research Center, by calling (540) 750-9626, 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 60 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. Sessions will take place in Roanoke, VA at the Fralin Biomedical Research Institute.

In 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. You will be provided with a list of available products. At the end of the session, you will be given samples of your preferred flavor of each product to use outside of the lab so that you may familiarize yourself with their effects.

In Sessions 2 and 3, you will be given a real amount of money (an "account balance") that you can use to purchase nicotine/tobacco products. The price of cigarettes will vary and you will complete these trials under different policy scenarios, including penalties for purchasing in an illegal marketplace. At the end of each 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. During the following 7 days after each session, you will be asked to use only the tobacco products you received during the study. During these two sessions, you will also be asked to complete some assessments about your use of nicotine/tobacco products and other questionnaires.

In Session 4, you will either visit the lab or receive a phone call to complete a subset of assessments about tobacco use and behavioral tasks.

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

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

- Provide a breath sample to test for recent nicotine use and smoking.
- Provide a urine sample to test for pregnancy, if applicable.
- Complete questionnaires about tobacco use and preferences.
- Between sessions 2 and 4, only use the study-provided tobacco/nicotine products purchased during study sessions 2 and 3.
- Notify the researchers if you cannot attend a scheduled session.

- Notify the researchers if experiencing any discomfort or desire to discontinue participation in 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 to not answer any questions or not respond to what is being asked of you without any negative consequences. 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 use any collected data unless you specifically request otherwise.

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. Risks include possible embarrassment and/or discomfort that may result from answering questions or completing tasks 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 during the 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., lightheadedness, dizziness, headache, irritability, sleepiness, decreased alertness, difficulty concentrating, impatience, sleeplessness, and increased eating). You may also not enjoy sampling/using some of the products. You may also experience some minor mouth, throat, or sinus irritation.

Additionally, because this experiment will allow you to 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 or become 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) 526-2136 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. Freitas-Lemos, the Principal Investigator at 540-526-2106 (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) . 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 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 a 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 tobacco product use or other study data.

If identifiers are removed from the 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.

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

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.'

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.

Compensation is distributed according to individual progress through sessions. You may receive up to $125 for participating in this study, according to the following:

Session 1 (up to $35)
- $10 for completion of the consent
- $15 for completion of the assessment surveys
- $10 for completing of the ETM demo

Session 2 (up to $40)
- $25 for product sampling
- $15 for completion of the Experimental Tobacco Marketplace session

Session 3 (up to $15)
- $15 for completion of the Experimental Tobacco Marketplace session

Session 4 (up to $35)
- $15 for the follow-up visit/session
- $20 bonus for completing the study

Additionally, you may receive the remaining balance if your purchase is consistent with your typical purchase behavior, reported in the last 30 days by the Timeline follow back. You may also receive additional compensation for your travel time, consistent with current Virginia minimum wage, or transportation may be provided (e.g., rideshare).

If you receive compensation greater than $600.00 for Virginia Tech 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 provided 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 insert your initials 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
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

INSTRUCTIONS:

- *Use this "TEMPLATE PROTOCOL (HRP-503)" to prepare a study protocol outlining your research plan.*
- *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as "N/A." For example, a simple survey might have many sections with "N/A." For subsections (e.g., 1.x or 8.x) you can mark as "N/A"if you are certain that the subsection is not applicable.*
- *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
- *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate "Amendment: Date" before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

PROTOCOL TITLE:

Include the full protocol title.

Promotion factors and mitigation strategies leading to illegal tobacco purchases

PROTOCOL NUMBER: #23-825

Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP).

PRINCIPAL INVESTIGATOR:

Full Name and Degrees: Roberta Freitas-Lemos, PhD
Department: Fralin Biomedical Research Institute at VTC
Telephone Number: 540 526 2106
Email Address: rflemos@vtc.vt.edu

FUNDING:

Sponsor(s): National Institutes of Health, National Cancer Institute - grant 5P01CA200512.
Funded already or in the proposal phase?: Funded
Is Virginia Tech the primary awardee or the coordinating center of this grant or contract? If not, list the primary institution: Medical University of South Carolina. This Study 2 is part of Project 3 of an NIH P01 Grant awarded to Medical University of South Carolina. Virginia Tech is receiving a subcontract

for Project 3. All data collection for this single site study will be carried out at Virginia Tech.

VERSION NUMBER/DATE:

Include the version number and date of this protocol. Versions should start at 1.0.

Click here to provide a response.

REVISION HISTORY:

Use this table to keep track of changes. Add more rows as needed.

Revision #	Version Date	Brief Summary of Changes (i.e., the different sections)	Consent Change?
9	1/3/2025	Removing Experiment 2, which will be submitted as its own IRB protocol.	No
10	5/27/2025	Updating statistical analysis plan and recruitment sample	No

Table of Contents

1.0 Study Summary

Study Title	Promotion factors and mitigation strategies leading to illegal tobacco purchases
Study Design	This experiment will examine the effects of promotion factors and mitigation strategies on illegal purchases. Exclusive cigarette smokers and dual cigarette/Nicotine vaping products (NVP) users, stratified by age, will complete multiple scenarios in the legal experimental tobacco marketplace (LETM)/illegal ETM (iETM). In both experiments, we will examine two promotion policies. In the full nicotine conditions, participants' preferred cigarettes and NVP products will be available in the LETM and preferred cigarettes will be available in the iETM. In the low nicotine conditions, a ban will permit only very-low nicotine cigarettes (VLNCs) in the LETM and preferred cigarettes will continue to be available in the iETM. In this experiment, we will apply one mitigation strategy (penalties) to test reductions in iETM purchases.
Primary Objective	To examine the effects of promotion factors and mitigation strategies on legal and illegal tobacco purchases for different tobacco-user types.
Secondary Objective(s)	N/A
Study Population	Cigarette smokers and dual cigarette/NVP users
Sample Size	N = 52 completers per experiment
Research Intervention(s)/ Investigational Agent(s)	Promotion factors and mitigation strategies.
Study Duration for Individual Participants	Session 1: Consent, Assessments (approximately 1h00). Session 2: First ETM session (approximately 30) Session 3: Second ETM session (approximately 30) Session 4: Follow-up (approximately 30-45min)
Acronyms and Definitions	NVPs: Nicotine Vaping Products NPPs: Nicotine Pouch Products NRT: Nicotine Replacement Therapy ETM: Experimental Tobacco Marketplace LETM: Legal Experimental Tobacco Marketplace iETM: Illegal Experimental Tobacco Marketplace FBRI: Fralin Biomedical Research Institute SES: Socio economic status VTCRC: Virginia Tech Corporate Research Center VLNC: Very Low Nicotine Cigarette

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives of this study:

Purpose: To examine the effects of promotion factors and mitigation strategies on legal and illegal tobacco purchases for different tobacco-user types.

2.2 State the hypotheses to be tested:

The primary hypotheses are: 1) a policy reducing the nicotine of conventional cigarettes will escalate purchases from the iETM, 2) penalties will suppress illegal purchasing relative to a no-penalty condition, and 3) dual cigarette/NVP users will be less responsive to the promotion factors (price and VLNCs) and more responsive to the mitigation strategies, compared to exclusive cigarette smokers.

3.0 Background

3.1 Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study:

The FDA report, Illicit Trade in Tobacco Products Implementation of an FDA Product Standard (2018, p.13), states:
"*. . . it is expected that there will still be a subset of consumers uninterested in switching products or in quitting tobacco products altogether, as well as those who believe they are unable to switch or quit. Discerning the reason for their product or brand loyalty is unnecessary for the purposes of this discussion; the result is that these individuals may seek tobacco products from an illicit market after a standard is in place. There is no way to determine with certainty the prevalence and extent to which an illicit market will occur after any particular tobacco product standard is in place, nor how long such a market might be sustainable.*"

Such consumer actions could result in some tobacco users seeking banned products from illegal sources that, in turn, may undermine the public health benefits of tobacco control. Indeed, considerable evidence shows that illicit trade in tobacco products is ongoing (1-3). Such products are increasingly available via internet purchase (market reaction) (4). Moreover, some non-commercial products contain adulterants that may exacerbate health risks (5). The tobacco science field has suggested several mitigation strategies (6,7), but testing the efficacy of these strategies before implementation has not been conducted, in part, because of the absence of appropriate empirical models.

Here we propose to examine some of these strategies in an experimental laboratory model of illicit purchases. Specifically, we have developed an Illegal Experimental Tobacco Marketplace (iETM). The iETM permits us to identify the number, type, and characteristics of tobacco users who would seek illegal tobacco products and the conditions that would induce them to seek that option. The critical questions we seek to answer are whether changes in product standards and availability

will engender illegal tobacco purchasing as a function of tobacco user type (e.g., exclusive combustible product users, and dual cigarette/NVP users). Understanding the user types and the relevant conditions will inform greater tailoring of policy to diminish consumer interest in an illegal market.

1. Joossens L, Raw M. From cigarette smuggling to illicit tobacco trade. Tob Control. 2012 Mar;21(2):230–234. PMID: 22345257
2. Gallagher AWA, Evans-Reeves KA, Hatchard JL, Gilmore AB. Tobacco industry data on illicit tobacco trade: a systematic review of existing assessments. Tob Control. 2019 May;28(3):334–345. PMCID: PMC6580768
3. Gilmore AB, Rowell A, Gallus S, Lugo A, Joossens L, Sims M. Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded "Project Star"report. Tob Control. BMJ Publishing Group Ltd; 2014;23(e1):e51–e61.
4. Barrera V, Malm A, Décary-Hétu D, Munksgaard R. Size and scope of the tobacco trade on the darkweb. Global Crime. Routledge; 2019 Jan 2;20(1):26–44.
5. Stephens WE, Calder A, Newton J. Source and health implications of high toxic metal concentrations in illicit tobacco products. Environ Sci Technol. 2005 Jan 15;39(2):479–488. PMID: 15707047
6. Ribisl KM, Hatsukami DK, Huang J, Williams RS, Donny EC. Strategies to Reduce Illicit Trade of Regular Nicotine Tobacco Products After Introduction of a Low-Nicotine Tobacco Product Standard. Am J Public Health. ajph.aphapublications.org; 2019 Jul;109(7):1007–1014. PMCID: PMC6603473
7. Chaloupka FJ, Edwards S, Ross H, Diaz M, Kurti M. Preventing and reducing illicit tobacco trade in the United States. Atlanta GA: Centers for. 2015;

3.2 Describe any relevant preliminary data:

In a series of online pilot studies, we investigated the demand for illegal nicotine and tobacco products in the iETM across several different policy scenarios. Most relevant to the current proposal, we examined the effects of a VLNC standard on preference for conventional, regular-nicotine cigarettes available in the hypothetical iETM. Exclusive cigarette smokers (N=52) chose to purchase in the LETM and iETM across five cigarette prices (½x, 1x, 2x, 4x, and 8x market price) and two nicotine contents (normal vs. VLNC). In the VLNC condition, participants were instructed that the FDA reduced nicotine in cigarettes resulting in a less satisfying product that failed to diminish craving. Results showed greater iETM purchases as a function of escalating cigarette cost (OR: 121.5; p-value <0.001). We also observed greater preference for illicit purchases when VLNCs are the only cigarettes available in the LETMt (OR: 16.8 ; p-value =0.002). These findings suggest that both price and product standards can impact illegal tobacco purchases. Additionally, we have recently published two other iETM studies. In the first

one, we have shown that individuals are more likely to make illegal purchases when product availability in the LETM is more restricted, and that the likelihood of purchasing illegal products was decreased as monetary penalties associated with the iETM increased (8). In the second study, we showed that vaping restrictions led individuals to increase illegal purchases in a regulatory environment (9). Taken together, it is suggested that availability and restrictions may play a role in illegal tobacco product purchasing.

8. Freitas-Lemos, R., Stein, J. S., Tegge, A. N., Kaplan, B. A., Heckman, B. W., Cummings, K. M., & Bickel, W. K. (2021). The illegal experimental tobacco marketplace I: effects of Vaping product bans. *Nicotine and Tobacco Research*, *23*(10), 1744-1753.
9. Freitas-Lemos, R., Stein, J. S., Tegge, A. N., Kaplan, B. A., Heckman, B. W., McNeill, A., ... & Bickel, W. K. (2022). Illegal Experimental Tobacco Marketplace II: effects of vaping product bans—findings from the 2020 International Tobacco Control Project. *Tobacco Control*, *31*(Suppl 3), s1-s9.

3.3 Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge:

An important aim of tobacco control is to reduce illegal purchasing. No study to date has experimentally compared the effects of promotion factors and mitigation strategies on purchasing behavior of illegal tobacco products. Therefore, a priori knowledge of factors that lead individuals to switch from legal to illegal marketplaces across novel and widely used tobacco products may forecast the impact of policies aiming to reduce illegal purchases.

4.0 Study Endpoints

*4.1 Describe the primary and secondary **study** endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing

Illegal tobacco purchases: The extent of substitution between the LETM and iETM (i.e., proportion spent in each marketplace of the total budget) will be our dependent variable.

*4.2 Describe any primary or secondary **safety** endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily*

encountered in daily life or during the performance of routine physical or psychological examinations or tests.):

This study will recruit adults who smoke cigarettes daily and who smoke cigarettes and use NVPs regularly. This study's procedures are not designed to increase daily nicotine use and we do not anticipate any increased risk to participants directly from this study, although there are risks of nicotine use and these are included in the risk section of this protocol and consent.

5.0 Study Design and Statistical Analysis Plan

5.1 Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy):

Participants will complete 1 to 2 ETM sessions, each with either a control or penalty strategy. In each ETM session, participants will complete both the full and low promotion factors. In the full promotion factor, their preferred cigarettes and other products will be available in the LETM and preferred cigarettes will also be available in the iETM. In the low promotion factor, a ban will permit only VLNCs in the LETM and preferred cigarettes will be available in the iETM. Control (i.e., no penalty) and penalty conditions will be completed in separate sessions and will be counterbalanced. Similarly, the full and low promotion factors will also be counterbalanced across participants.

5.2. *Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures)*:

We will use linear modeling approaches, including linear mixed-effects models, to evaluate how experimental conditions influence participant behavior. These models will assess differences in outcomes such as purchasing behavior, demand levels, and sensitivity to price changes across various experimental conditions (e.g., promotional strategies and policy interventions) and participant groups (e.g., different user types).

Independent variables will include participant group, experimental condition, and product price. Interaction terms will be included to examine whether the effects of experimental conditions differ by participant group or across price levels. Random intercepts will be used to account for individual differences in baseline behavior.

Key dependent variables will include indicators of demand, such as baseline purchasing and price sensitivity. Demographic factors like age, sex, and socioeconomic status will be included as covariates to control for confounding influences.

Post-hoc contrasts will be conducted to explore specific differences between conditions and participant groups, based on the overall model results. Multiple comparison corrections will be applied to reduce the risk of false positives. Effect sizes and confidence intervals will be reported along with significance levels to describe the magnitude and reliability of the findings.

This analytic strategy will allow us to:

1. Differences in iETM purchases between promotion factors and mitigation strategies.
2. Changes in illegal purchasing between penalties and control.
3. Differences in the response to promotion factors and mitigation strategies between the two user types.

Additional exploratory analyses may be conducted if relevant patterns emerge in the data.

6.0 Setting

6.1 Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where the team will perform the research procedures.*
- *Describe the composition and involvement of any community advisory board(s).*
- *For research conducted in other locations, describe:*
  - *Site-specific regulations or customs affecting the research at those locations.*
  - *Local scientific and ethical review structure at those locations. Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

Location of Recruitment:
Participants will be recruited from the Roanoke-Blacksburg and surrounding areas via flyers, word of mouth referrals, and electronic advertisements. To the extent possible, we will attempt to minimize obstacles to participation. For example, travel barriers will be

addressed by providing transportation or parking costs to participants, and scheduling barriers will be minimized by offering a flexible session schedule.

Location of study:
All methods and measures will be conducted using standard operating procedures at the Fralin Biomedical Research Institute (FBRI) at VTC, the Virginia Tech Corporate Research Center (VTCRC) or a designated site. All staff (including recruitment staff) will have completed human subjects' protection and research training. We have a history of successful recruitment of cigarette smokers and dual cigarette/NVP users. All participants will enroll on a voluntary basis and sign an IRB-approved consent form prior to study participation.

7.0 Study Intervention(s)/Investigational Agent(s)

7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:

- *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
- *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
- *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

This study does not involve any smoking cessation interventions. This study does involve experimental manipulation of cigarette product price to understand consumer's behavior. Participants will be provided with commercially available tobacco/nicotine products to use during the study, such as NVPs.

7.2 List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use:

The range of products available to sample and purchase includes: cigarettes, chewing tobacco, nicotine gum, nicotine lozenges, nicotine patches, NPPs, NVPs, VLNCs, and snus. All the products that will be available to sample and purchase are FDA-approved and available in the real world.

7.3 List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher's recommendation for each of those devices:

Participants will be provided with a NVP and instructed how to use according to the manufacturer specifications.

7.4 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

N/A

8.0 Procedures Involved

8.1 Describe and explain the study design:

Participants will complete 2 ETM sessions, each with 10 screens (i.e., marketplaces). During the first ETM session, participants will complete 2 conditions. In one of them participants' preferred cigarettes and NVP, as well as other nicotine products will be available in the LETM, and preferred cigarettes will also be available in the LETM (i.e., full-nicotine condition). In the second, a ban will permit only VLNCs in the LETM, as well as NVP and other tobacco products, whereas participants' preferred cigarettes will be available in the iETM only. Within each condition, 1 mitigation strategy (penalty) will

be employed, as well as a control mitigation strategy (i.e., no penalty). This will permit the investigation of the effects of promotion factors and mitigation strategies on illegal purchases.

8.2 Provide a description of:

- *All research procedures being performed*
- *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

Participants will complete 3-4 sessions as follows: 1) informed consent and assessment session, 2/3) one or two ETM sessions, and 4) follow-up in person session or phone call. Sessions 1 and 2 will be separated by an at-home sampling phase. ETM sessions will be separated by an at-home product use phase.

Session 1) In both experiments, in the consent and initial assessment session, participants will go through standard consent procedures and then provide a breath sample to confirm recent levels of smoking. Participants will complete a timeline follow-back (TLFB) to assess the previous month's smoking, and consumption of nicotine products, and to determine the ETM budget. A survey containing demographics questions and nicotine/tobacco-related assessments will be administered (Questionnaire on Smoking Urges-Brief, Heaviness of Smoking Index, Perceived Health Risk, Product Evaluation Scale, Intention to transition and/or quit, Tobacco awareness and Hypothetical Purchase Task for conventional cigarettes and VLNCs. At the end of the session, participants will experience a trial of the ETM that will be used in the next session. For the at-home sampling phase participants will be provided single-user/individual NVP devices. A research assistant will read through the manufacturer instructions on how to use the products with the participant. If needed, the informed consent and initial assessment session can be on different days. For the sampling phase, participants will be provided with the most preferred flavor of NVP, and VLNC to sample during the sampling period. Participants may also be provided with a sample of any other commercially available tobacco product they wish to examine and try. Importantly, we will instruct participants to sample the VLNC products before other products, and after being abstinent during the prior night. We will send each participant a text message as a reminder. Participants will sample VLNCs only before the first ETM session.

Sessions 2-3) In both experiments, participants will undergo two different scenarios in a counterbalanced order in the ETM session. In one scenario, the conventional cigarettes available will be full strength, and in the other, VLNCs will be the only cigarettes available. In each ETM session, participants will complete one control and one penalty mitigation strategy under full and low promotion factors. Each ETM session will include 10 trials assessing different cigarette prices (5 trials for the full and 5 for the low promotion factors). In every trial, participants will be informed of the currently applicable

promotion factor and mitigation strategy. Then, participants will be able to view, browse, and purchase from either or both of the two different marketplaces: the LETM and the iETM. The first and second sessions will be separated by approximately 3 days. ETM sessions will be separated by approximately 1 week. During the second ETM session, participants will complete the mitigation strategy that they did not go through in session 1. For example, if they completed the control mitigation in session 1, then they will complete penalties in session 2.
Additionally, in each ETM session, participants will buy tobacco products to use throughout the next 7 days. Participants will complete a total of 10 purchasing trials for 7 days' worth of products. After each ETM session, one trial will be drawn randomly, and purchased products during that trial will be given to participants.
For approximately seven days following the ETM session(s), participants will be asked not to use or purchase any outside tobacco/nicotine products and not to sell or give away any of their purchases.

Session 4) In the follow-up session, participants will complete a timeline follow-up to assess the previous week recent smoking, and consumption of nicotine products. A survey will administer nicotine/tobacco-related assessments (Perceived Health Risk, Product Evaluation Scale, and Hypothetical Purchase Task for conventional cigarettes and VLNCs. Session 4 will be conducted either in-person or via phone or Zoom.

8.3 Describe:

- *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
- *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
- *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
  - *Screening questionnaires*
  - *Survey(s), including online surveys*
  - *Demographic questionnaire(s)*
  - *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
  - *Focus group guide(s)*
  - *Other documents used to collect data*

Participation in this study is completely voluntary and participants may choose not to participate at any time.

Participants will be given an FDA-approved NVP and VLNC to sample/use during the course of this study. Research personnel will provide detailed instructions and demonstrations to assure proper use according to the manufacturer specifications.

Information and data from participants will be collected by research staff and from self-reported surveys. Examples of the assessments described in section 8.2 are attached.

8.4 What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection:

All of the survey and questionnaire data will be collected using Qualtrics, an online survey platform used to develop, administer, and collect participant data in a secure password-protected database.
ETM data will be collected using an experimental online store containing several products, wherein participants will be able to choose from a pre-established catalog. All ETM tasks will be performed on a computer.

8.5 Who will transcribe or code audio and/or video recordings?:

N/A

8.6 Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets <u>all</u> the following criteria for alteration of consent (deception is considered an alteration of informed consent):

- *The research involves no more than minimal risk to the subjects*
- *The alteration will not adversely affect the rights and welfare of the subjects*
- *The research could not practicably be carried out without the alteration/deception*
- *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

N/A

8.7 If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur:

N/A

9.0 Data and Specimen Long Term Storage and Use

9.1 If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed:

All participant data, including electronic data, will be stored in secure places to protect confidential participant information. Secured places will include locked filing cabinets, locked rooms accessible only to study personnel, and/or password-protected databases. Moreover, all data will be quality controlled in preparation for data analyses. All discrepancies in data entry will be checked against the raw data source, and the correct data entry will be used. All data entered into spreadsheets and databases will be coded by participant ID number and not by name (i.e., first and last name). Additionally, all entered data will be backed up on secure password-protected servers. Computers used in the studies will also be password protected, accessible only by study personnel. IRB regulations will be strictly adhered to in the conduct of the proposed research. Specifically, prior to implementation of any protocol changes, amendments will be submitted to the IRB for approval. Consistent with our other NIH-funded projects, data will be retained for a minimum of 3 years after publication of the results.

9.2 For specimens, list the data to be stored or associated with each specimen:

N/A

9.3 Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens:

Investigators will adhere to all NIH requirements regarding data sharing. Participant data collected in this project will be de-identified before sharing for analysis outside of the study team. As part of this process, all investigators will be required to agree to the

following conditions: 1) will adhere to the reporting responsibilities; 2) will not redistribute the data beyond the requesting individual and named collaborators; 3) will give appropriate acknowledgment; 4) will not use the data for commercial purposes; and 5) will obtain appropriate ethical approvals.
Results from research conducted will be shared and disseminated, including: regular project meetings, annual meetings, symposia, workshops, and/or conferences for related groups. Manuscripts will be written and submitted for publication in peer-reviewed journals/conferences, following the NIH Public Access Policy guidelines. All necessary ethical approvals will be obtained.

Data requests will be reviewed by the principal investigator and data will be shared with the expectation of acknowledgment of funding source and primary study team.

9.4 Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed:

All screened participants are assigned study IDs that are thereafter associated with all collected data, whether paper or electronic. The electronic de-identified data is stored on a shared server which is password protected and only accessible to members of the research team on the VT IRB approved protocol. Non-electronic data that is collected is stored in study binders identified only by study ID. These binders are stored in a locked file room inside a locked office within ARRC, accessible to only members of the research team on the VT IRB approved protocol.

Study ID and full name are available together electronically only in REDCap (Harris et al. 2009), a widely used secure web-based application that enables us to build and maintain a participant database. Specifically, we use REDCap to collect demographic and other screening criteria for eligibility for study enrollment. This service is password protected and has been approved by Virginia Tech IRB. Personnel with access to REDCap will be approved on the IRB protocol and will be limited to personnel directly involved in recruitment, enrollment, and eligibility verification. We use a REDCap pre-screening survey to determine appropriateness for enrollment of ongoing studies within our lab. REDCap assigns a number to each survey completer and we use this ID for study data. If participants agree to be contacted about future research opportunities, we retain their information in the secure REDCap database separate from any study data.

Non-VT co-investigators, including Dr. Tracy Smith from MUSC will have access only to deidentified data.

1. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–81. doi:10.1016/j.jbi.2008.08.010

9.5 Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:

☒	*Name*
☒	*Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)*
☒	*Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)*
☒	*Phone numbers*
☐	*Fax numbers*
☒	*Electronic mail addresses (e-mail)*
☒	*Social Security numbers*
☐	*Medical record numbers*
☐	*Health plan beneficiary numbers*
☐	*Account numbers*
☐	*Certificate/license numbers*
☐	*Vehicle identifiers and serial numbers, including license plate numbers*
☐	*Device identifiers and serial numbers*
☐	*Web Universal Resource Locators (URLs)*
☐	*Internet protocol (IP) address numbers*
☐	*Biometric identifiers, including finger and voice prints (audio recording)*
☐	*Full face photographic images and any comparable images (including video recording)*
☐	*Student record number or identification number*
☐	*User name for online or computer accounts*
☐	*Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data):* Click here to explain.

10.0 Sharing of Results with Subjects

10.1 Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject's primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects:

We will not share study results or individual results directly with the study participants or others.

11.0 Study Timelines

11.1 Describe:

- *The duration of an individual subject's participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
- *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
- *The amount of time expected for the investigators to complete this study including primary data analyses.*

1) Participant's schedule

The participation of one subject is expected to take approximately 3 weeks. Session 1 (Consent, Assessments) is estimated to take approximately 1h. Each ETM session is expected to take approximately 30min. Session 4 (follow-up) is estimated to take approximately 30 to 45 minutes.
*Note that participants will sample/use products between sessions 1 and 4.

2) Study timeline

The study team has projected this study to take approximately 1.5 years to complete enrollment, data collection and data analysis.

12.0 Inclusion and Exclusion Criteria

12.1 Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management:

Our team has developed a specific screening for all smoking-related studies in our lab, which has been uploaded. The screening process occurs prior to enrolling participants

into our research protocols, to effectively decrease attrition in our studies by ensuring that participants meet all inclusion/exclusion criteria prior to enrolling into a study.

12.2 Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France):

Inclusion criteria:
- Provide informed consent
- Be at least 21 years of age or older
− Provide a breath sample for measuring carbon monoxide (CO ≥ 8 ppm)
- Stable tobacco use patterns for at least two months

For exclusive cigarette smokers:
- Smoke at least 10 cigarettes daily and do not use NVPs regularly (no more than 9 times in the last month).
For dual cigarette/NVP users:
- Smoke at least 10 cigarettes daily and use NVPs at least 3 times in a week (report use of closed nicotine salt system)

Exclusion criteria:
- Have plans to move out of the area
- Have a serious or unstable physical or mental health condition
- Taking a tobacco cessation medication or medication that interferes with nicotine metabolism, motivation or reinforcement
- Report concrete, immediate plans to alter/quit using their usual nicotine products at the beginning of the study
- Being pregnant or lactating

12.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)

- *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
- *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
- *Prisoners (including all incarcerated individuals)*
- *Adults not capable to consent on their own behalf*

This study will focus on cigarette smokers and dual cigarette/NVP users. We will not include individuals under the age of 21 in compliance with Virginia state law. Minors, pregnant or lactating women, prisoners, and adults not capable of consent on their own behalf will be excluded from this study.

13.0 Vulnerable Populations

13.1 If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:

- *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).*
- *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
- *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
- *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the "CHECKLIST: Minors (HRP-416)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information in this protocol.*

Virginia Tech Students might participate in the study if they meet the inclusion criteria, although students will not be directly recruited because of their status. However, no students that have had or have any relationship with this lab will be included.

14.0 Number of Subjects

14.1 Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow):

Our sample sizes are based on repeated measures within-between interaction ANOVA design using a medium effect size (f=0.25) and 80% power. Note the effect sizes observed in preliminary data ranged from f=0.29 to f=1.05. Given that the mitigation strategies used in these experiments are untested (i.e., health communication, NRT availability, and penalties), we conservatively selected a medium effect size of f=0.25. In order to account for multiple testing, we will control for five comparisons in each experiment; therefore, we use an alpha of 0.01. For this study, we require a sample size of 52 (26 per user type) participants to complete the study when using repeated measures with 2 user-types and 2 measurements per participant. Due to the four-session design, we expect 25% attrition across the sessions; therefore, we will recruit approximately 80 participants (40 per user type) to enroll in each of the two experiments. Note that this study includes more than two measurements per participant, but only two were considered in the calculations to maximize power. In addition, age is associated with user type; therefore, we will stratify each user type to have a similar distribution of ages.

14.2 If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites:

N/A

14.3 If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures:

We have developed and are currently using a specific screening for smoking-related studies in our lab. The screening process occurs prior to enrolling participants into our research protocols. We anticipate enrolling about 80 participants to complete a total of 52 participants.

14.4 If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately:

All participants will undergo all four sessions unless they withdraw consent.

15.0 Recruitment Methods

15.1 Describe when, where, and how you will recruit potential subjects:

Participants will be recruited from the community via flyers, word of mouth via others outside of the research team, and digital versions of the flyers. Participants will be contacted if they have given prior permission (through a previous informed consent form) or by completion of a confidential pre-screening questionnaire. Services from mailing list companies may be used.

15.2 Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym):

Participants will usually be from the Blacksburg-Roanoke and surrounding areas.

15.3 Describe the methods that you will use to identify potential subjects:

Flyers and ads will generally describe the study and direct potential participants to either call our lab to screen over the phone or to complete our online pre-screener. Participants may also pre-screen in person.

15.4 Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.

- *For flyers, attach the final copy of printed flyers.*
- *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
- *For email recruitments, please include the subject line.*

- *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*
- *Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

Flyers to be used in community and online postings are attached.

Compensation for this study is for time and effort and an additional incentive for study completion.

1) Time and effort:

Compensation is distributed according to individual progress through sessions. Participants may receive up to $125 for participating in this study, according to the following:

Session 1 (up to $35)
- $10 for completion of the ETM demo
- $10 for completion of the consent
- $15 for completion of the assessment surveys

Session 2 (up to $40)
- $25 for product sampling
- $15 for completion of the Experimental Tobacco Marketplace session

Session 3 (up to $15)
- $15 for completion of the Experimental Tobacco Marketplace session

Session 4 (up to $35)
- $15 for the follow-up session/visit
- $20 bonus for completing the study

2) Travel:

In addition to the above compensation for participation, participants may receive additional compensation for travel time, e.g. $12.00 per hour, consistent with Virginia minimum wage. Research personnel may also arrange and pay for cab, rideshare or public transportation.

To allow for payments that are both convenient and rapidly available, we will pay participants with reloadable prepaid cards through Greenphire ClinCard (www.greenphire.com), an FDIC-insured payment provider that specializes in clinical trial stipend payments that comply with IRB privacy regulations and considerations. At the beginning of the study, participants will receive a prepaid MasterCard debit card that can be used anywhere that accepts MasterCard. As payments are earned in the course of the study, additional funds will be added to the account for that participant. Funds are immediately available when added and participants can check their balance as desired.

16.0 Withdrawal of Subjects

16.1 Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent:

Participants could be withdrawn from the study if they exhibit or report 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 participation if a participant's answers or performance suggest that it is not safe and appropriate for them to continue in the study.

16.2 If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention):

If a participant is withdrawn from the study, they will be informed of the reason(s) for terminating their participation. If a participant is withdrawn or voluntarily discontinues, their compensation for the study will be pro-rated accordingly.

16.3 Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires):

If a participant is withdrawn from the study for any reason, they will be removed from the remainder of the study.

17.0 Risks to Subjects

17.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include for the IRB's consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate "No risk" or "N/A." Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate "The investigators are not aware of any risks from participation in this study." or "No more than risks than are found in everyday life." The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:

- *Physical (e.g., potential for pain, discomfort, infection)*
- *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
- *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
- *Legal (e.g., potential for disclosure of illegal activity, negligence)*
- *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects' knowledge or consent, breach of confidentiality/security)*
- *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

There will be no direct costs for participation, although there are risks.

1. Possible embarrassment: This may result from answering questions that participants consider sensitive. Some of our questions will ask for information about medical and psychiatric conditions and/or drug use.

2. Possible discomfort: There is also the possibility that participants may become bored or frustrated during the research sessions.

3. Loss of confidentiality: The research team will employ every effort to maintain participant confidentiality, however the loss of confidentiality is a potential risk.

4. Adverse effects associated with nicotine use: Because the present experiment involves self-administering nicotine products, participants might experience adverse effects associated with the use of such products (e.g., nausea, vomiting, dizziness, diarrhea, weakness, rapid heartbeat, minor increase in throat or sinus irritation).

5. Adverse effects associated with nicotine withdrawal: participants might experience adverse effects associated with withdrawal from nicotine (e.g., dizziness, headache, irritability, sleepiness, decreased alertness, difficulty concentrating, impatience, sleeplessness, and increased eating).

6. Participants might feel uncomfortable being exposed to a hypothetical illegal marketplace.

Due to the investigative nature of this study, there may be other risks that are currently unknown.

17.2 Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)

Informed Consent. All consenting methods will be conducted using standard operating procedures, and all study personnel will be provided with human subjects protection training. All participants will enroll on a voluntary basis and sign an IRB-approved consent form prior to study participation.
Protections against risk. Participants will be screened using questionnaires for medical contraindications (e.g., pregnancy, recent myocardial infarction) and current unstable medical illnesses. Participants will be free to withdraw from the study at any time. In addition, if participants develop medical problems or experience adverse events during the course of the study, assessments to determine whether participants should continue in the study and/or continue to use products will be conducted and necessary referrals will be provided. Participants will also be told that they can stop using the study products at any time.

The risks enumerated above will be addressed by the following:
1. Possible embarrassment: Participants are free to refuse to answer questions and withdraw from the study at any time.

2. Possible discomfort: Participants will be able to select a date and time of their choice to start the study. They will also be given breaks during sessions, if desired. To increase data validity and reliability, breaks might be incorporated within the ETM session.

3. Loss of confidentiality: The use of ID numbers for participants, and keeping all data in secure storage locations will help protect confidentiality. Password protected computer databases will have coded identifiers. Master databases linking subject names to study ID numbers will be kept separate from the data. These screening, monitoring, and confidentiality procedures have been in effect for decades and for thousands of participants across the various protocols employed by our group across various institutions.

4. Adverse effects associated with nicotine use: Participants will be informed of the potential adverse effects prior to sampling nicotine products.

5. Adverse effects associated with nicotine withdrawal: Participants will be informed of the potential adverse effects of stopping use of nicotine products.

17.3 If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device:

The use of study products may have risks to participants that are currently unforeseeable.

17.4 If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant:

Nicotine/tobacco use can be a risk to an embryo or fetus. However, during the consent session, female participants will be tested for current pregnancy. Currently pregnant females will be discontinued from participation.

17.5 If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships):

N/A

18.0 Potential Benefits to Subjects

18.1 Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB's risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document:

Participants will not directly benefit from participating in this study. However, the current study may help identify effective methods of assessing the use of tobacco products as well as policy changes, which may help improve healthy decision-making in the future.

18.2 If applicable, specify that there are no anticipated direct benefits for participants:

There are no anticipated direct benefits for participation in this study, though participants may enjoy learning about research processes

19.0 Data Management and Confidentiality

19.1 Describe procedures that you will use for quality control to ensure validity of collected data:

The PI will oversee monitoring of the data collection procedures. These procedures will be reviewed regularly in a number of settings. For instance, issues pertaining to data validity and integrity will be addressed formally during regularly scheduled study personnel meetings in which study personnel, including the PI, will be in attendance. Issues pertaining to participant safety also will be addressed at these meetings and in between meetings as needed

19.2 Describe any existing data or biospecimens you will obtain as part of this study. Include:

- *Variables or samples to be obtained*
- *Source of the data or specimens*
- *Your authorization to access or receive the data or biospecimens*
- *Whether the data or biospecimens are publicly available*
- *Whether the data or specimens you receive will contain identifiers*

We may collect urine samples to test for pregnancy and breath samples for carbon monoxide to assess recent levels of smoking. All tests will be used to obtain the desired measurement and then appropriately discarded.

19.3 Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.:

Access to study data will be limited to study personnel who have completed human subjects research protections and Good Clinical Practice training and who have been delegated the responsibility of data collection, management, or analyses by the PI.

All screened participants are assigned study IDs that are thereafter associated with all collected data, whether paper or electronic. Electronic de-identified data will be stored on shared servers that are password-protected. Non-electronic data that are collected are stored in participant specific binders identified only by study ID. These binders are stored in a locked file room inside a locked office within ARRC. Study ID and full name are available together electronically only in REDCap (Harris et al. 2009), a widely used secure web-based application that enables us to build and maintain a participant database. Specifically, we use REDCap to collect demographic and other screening criteria for eligibility for study enrollment. This service is password protected and has been approved by the Virginia Tech IRB.

In addition, as an NIH-funded study, this protocol has a certificate of confidentiality.

19.4 For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center):

N/A

19.5 Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).

- *What information will be included in the long term storage of data or specimens?*
- *How long will the data or specimens be stored?*
- *Where and how data or specimens will be stored?*
- *Who will have access to the data or specimens during long term storage?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data or specimens be shared or transported?*
- *When and how will personal identifiers be destroyed?*

All behavioral data collected in this study (including participants' characteristics, tobacco related assessments and tobacco purchasing) will be retained and destroyed in accordance with the Center's policy that requires a 3-year retention period following final publication of the data. To secure study data, computer databases will have coded identifiers, only ID numbers will be used, data will be kept in secure locations and/or in locked offices. Access to study data will be limited to study personnel who have completed the IRB Human Subjects Training and who have been delegated the responsibility of data collection, management, or analyses by the PI. Currently, there are no plans for data to be sent/transmitted outside the research group. In the event that someone requests the data, only de-identified data will be shared by the lead and principal investigator through a secure virtual server. Personal identifiers may be kept long term if participants express interest in being considered for future research.

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Describe the steps that you will take to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained):

The amount of private information collected in this study is minimal. The information collected is necessary to assure subject safety, completion of the study and proper compensation. Procedures to keep the information safe are described in section 9.4.

20.2 Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research):

The locations where this study will be conducted have private offices, individualized computer testing and interview rooms. In cases in which private information is collected, the participant is in a private interview room with trained research personnel. The lab is equipped with white-noise machines to reduce excess noise and maintain confidentiality. All participants are informed that their information is confidential.

20.3 Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan:

Participants who have previously given consent to be contacted for future studies will be searchable in the REDCap database. Eligibility criteria, based on demographics and current nicotine/tobacco use, may be reviewed to contact potentially eligible participants for this study.

20.4 Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:

- ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
- *Sexual discrimination and/or sexual violence that involves a student*
- *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
- *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
- *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

We do not expect any required reporting to occur as a result of our research questions and data collection methods. However, as a safeguard, we include in our consent form that any instances of child or elderly abuse or intent to harm self or others will be reported. Any cases of disclosure or signs of sexual discrimination and/or sexual violence will be reported according to Title IX report procedures.

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety monitoring is required when research involves greater than minimal risk and is sometimes appropriate for other studies.

21.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
- *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the safety data and with what frequency.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

The study leader and PI will review any reported health changes or adverse events and report as necessary.

22.0 Compensation for Research Related Injury

22.1 If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any:

N/A

22.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research:

N/A

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare:

There are no costs to participate in this study. To the extent possible, we will attempt to minimize obstacles to participation. For example, travel barriers may be addressed by providing transportation or compensation for additional time needed to travel to the research center.

24.0 Consent Process

24.1 Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.

Describe the following:

- *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
- *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple*

online survey studies, you can typically present the consent information immediately before subjects begin participation.

- *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
- *Please review "SOP: Informed Consent Process for Research (HRP-090)" for recommended procedure. Describe your process, being sure to include:*
  - *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
  - *The time that will be devoted to the consent discussion*
  - *Steps that you will take to minimize the possibility of coercion or undue influence*
  - *Steps that you will take to gauge or ensure the subjects' understanding*

Participants will be provided with a copy of the consent form following phone or online screening by email or mail when possible. To accommodate "walk-in" study screens and/or participants unable to receive email or physical mail (e.g., without physical address, email address, or access to a computer), we will provide a hard copy of the consent form to review. In all cases, participants will be given as much time as needed to review the consent and ask any questions. Participants will also be informed that they may choose to take the consent with them and return at a later date to enroll into the study. During the consent process, participants will be given adequate time in a quiet room to read (or further review) the informed consent form.

Research staff will review each element of the consent form with the potential participant. The potential participant will be given the opportunity to ask questions and will have as much time as needed to decide whether they would like to participate in the study. Study personnel will reiterate that the potential participant can choose to decline participation in the study at that time or at any time thereafter without consequence. The potential participant and personnel obtaining consent will sign the consent form after the potential participant verbally states that they understand the conditions of the study, have no more questions, and choose to participate. Participants unable to provide informed consent for themselves will not be eligible.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*

- *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
- *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

Non-English speakers will not be recruited.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- *Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

N/A

Subjects who are not yet adults (minors: infants, children, teenagers)

- *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
  - *For research conducted in Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "minor."*
  - *For research conducted outside of the state, please describe the legal requirements for the definition of "minor."*
- *Describe the process for obtaining parental permission.*
  - *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
  - *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*
- *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will*

use to determine these individuals' authority to consent to the minor's general medical care.

- *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
- *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
- *Attach parental permission and minor assent forms or scripts in Protocol Management.*

N/A

Adults Unable to Consent

- *Describe the process you will use to determine whether an individual adult is capable of consent.*
- *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
  - *For research conducted in the Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "legally authorized representative."*
  - *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
- *Describe the process for assent of the subjects.*
  - *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
  - *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
  - *Describe whether and how you will document assent.*

N/A

25.0 Process to Document Consent in Writing

25.1 Consult "SOP: Written Documentation of Consent (HRP-091)" for recommended procedures, and describe whether and how consent of the subject will be documented in writing:

Informed consent will include name and date from personnel and participants. In addition, a copy of the consent form (paper or electronic) will be offered to the participant.

25.2 If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins):

N/A

25.3 If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You should use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script:

Consent document is attached.

26.0 Resources Available

26.1 Describe the resources available to conduct the research. For example, as appropriate:

- *Describe the PI's availability to supervise the research.*
- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how*

many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

The organizational structure of the study team involves overall leadership by Dr. Roberta Freitas-Lemos, who will assume full responsibility for all aspects of the project, including design and participant eligibility. Dr. Freitas-Lemos will oversee recruitment and retention of participants. She will also oversee and delegate to the Co-Investigators and other study personnel the responsibility of training, consenting procedures, and data collection. The Research Coordinator(s) and Research Assistant(s) will be trained and supervised as appropriate for any delegated study procedures. Behavioral data analysis will be overseen by Dr. Freitas-Lemos and conducted by the Co-Is and the Statistician. All staff involved in the conduct and/or monitoring of this study will have completed the IRB Human Subject Protection Training and Good Clinical Practice Training. Documentation of training will be maintained. The PI will be responsible for continuous data and safety monitoring of all participants enrolled in this study. In terms of standard operating procedures, trained research personnel will administer all assessments.

Participants will be recruited from the community via flyers, word of mouth referrals, and electronic advertisements (e.g., Craigslist, Facebook, Reddit). To the extent possible, we will attempt to minimize obstacles to participation. For example, travel barriers will be addressed by providing transportation to participants, and scheduling barriers will be minimized by offering a flexible session schedule. All methods and measures will be conducted using standard operating procedures, and all personnel will be provided with human subjects' research training. We have a history of successful recruitment of smokers. All participants will enroll on a voluntary basis and sign an IRB-approved consent form prior to study participation. Note that we have been successfully recruiting cigarette smokers and e-cigarette users in our community for the past 10 years.
As far as facilities, the Addiction Recovery Research Center is part of the FBRI, located in Roanoke, Virginia. Multidisciplinary research projects include examining the effects of behavioral interventions as potential treatments for substance use disorders. ARRC also develops potential computerized therapies, applies principles from behavioral and neuro-economics to the understanding of addiction, and assesses nicotine product abuse liability.
ARRC resides on the 3rd floor of the FBRI and consists of several laboratories for clinical research. ARRC has private offices, individualized computer testing and

interview rooms. The lab has a ventilated, negative air pressure smoking laboratory that is equipped with computers and five additional behavioral booths, and a conference room. The research space also includes an adjacent male and female restroom with one-way observation windows and connecting stainless steel specimen pass-through cabinets. Office space for PI Freitas-Lemos, Co-Investigators, Project Coordinators, Postdoctoral Associates, and Research Coordinators/Assistants is provided in the FBRI. The ARRC office suite has a copy machine, fax machine, network printer, scanner, and storage space for participant files and supplies as well as comfortable waiting rooms with entertainment (e.g., magazines, television, etc.) for research participants.

VTCRC has a conference room, private offices, individualized computer testing and interview rooms plus a network printer and access to secured shared servers.

27.0 Multi-Site Research

Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.

N/A