CigVent Proj-003

Effects of Cigarette Filter Ventilation on Substitution in the Experimental Tobacco Marketplace in Tobacco Cigarette Smokers: Experiment 1

NCT03306173

Study Protocol

09/16/2021

Once complete, upload this form as a Word document to the IRB Protocol Management System:

https://secure.research.vt.edu/irb

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☒ **No**

☐ **Yes,** explain:

1.2 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

☐ **No,** go to question 1.3

☒ **Yes,** answer questions within table

IF YES
Provide the name of the institution [for institutions located overseas, please also provide name of country]**: Carilion Hospital**
Indicate the status of this research project with the other institution's IRB: ☐ Pending approval ☐ Approved ☐ Other institution does not have a human subject protections review board ☒ Other, explain: **Human subject activities covered in this protocol.**
Will the collaborating institution(s) be engaged in the research? (http://www.hhs.gov/ohrp/policy/engage08.html) ☒ No ☐ Yes
Will Virginia Tech's IRB review all human subject research activities involved with this project? ☐ No, provide the name of the primary institution: ☒ Yes *Note: primary institution = primary recipient of the grant or main coordinating center*

1.3 IS THIS RESEARCH FUNDED?

☐ **No,** go to question 1.4

☒ **Yes,** answer questions within table

IF YES
Provide the name of the sponsor [if NIH, specify department]: **NIH/National Institute on Drug Abuse**
Is this project receiving federal funds? ☐ No ☒ Yes **If yes,** **Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?** ☐ No, all human subject activities are covered in this IRB application ☐ Yes, however these activities will be covered in future VT IRB applications, these activities include: ☒ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: **16-472; 17-244** ☐ Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows: ☐ Other, explain: **Is Virginia Tech the primary awardee or the coordinating center of this grant?** ☐ No, provide the name of the primary institution: ☒ Yes

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY? *For example – government / industry proprietary or confidential trade secret information*

☐ **No**

☒ **Yes,** describe: **This project uses investigational reduced nicotine cigarettes manufactured by the National Institute on Drug Abuse for use in resarch studies. NIDA holds the proprietary master file for these cigarettes, and their use in research studies needs to be approved by the FDA Center for Tobacco Products. Under this oversight, any serious adverse events that occur with these products will be reported to the FDA.**

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT

AGENT OUTSIDE THE U.S?

☒ **No**

☐ **Yes**

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

Abuse liability of reduced nicotine content cigarettes: Purchasing and e-cigarette substitution IRB
v.4
09/15/2021

With the recently acquired mandate of the FDA to regulate the rapidly increasing market of tobacco products, research that can inform these regulations is vital. Before modifying the tobacco product marketplace through regulatory action, it is important to understand how specific features of tobacco products influence the choices to purchase and consume that product. The long-term goal of this line of research is to build an evaluative framework to assess how different aspects of tobacco products that may be subject to regulatory action (e.g., flavor, nicotine content, packaging) influence decisions to purchase and consume those products across a range of prices. To craft effective regulations, it is important to understand how specific features of tobacco products that may be subject to regulatory action influence the choice to purchase and consume that product.

Economic demand analyses quantify the relationship between the cost of a commodity and population-level measures of consumption of that commodity. Behavioral economic demand analyses are analogous to these population-level analyses, but can be used to understand the level of motivation to consume a product on either an individual or small group level, including cigarettes (Bickel et al., 1995; MacKillop et al., 2008). This level of analysis allows for experimental manipulations to be made on variables of interest. By quantifying how consumption decreases as costs to obtain and consume a product increase, important indices of demand are obtained. These indices can be grouped into two main measures of consumption, demand intensity and demand elasticity, which are associated with use level and dependence severity (MacKillop et al., 2008, 2009, 2010; Murphy et al., 2011). Demand intensity is the amount of the commodity consumed when available at a very low cost approaching free, and demand elasticity quantifies the degree to which the individual is willing to increase monetary or effort-based expenditures to maintain the same level of consumption as costs increase. Elasticity of demand has been shown to be a characteristic of the drug itself and independent of drug dose for many drugs including nicotine (Bickel et al., 1991; Hursh & Roma, 2013; Hursh & Silberberg, 2008; Hursh & Winger, 1995).

A fundamental observation of economics is that the type and number of products in a marketplace can alter a commodity's demand elasticity as well as the type and degree of interaction among those products. As a result, the ability to achieve the tobacco control goals of reducing the consumption of a particular product may be enhanced or diminished via the economic processes of substitution and complementarity (see Bickel, DeGrandpre, et al., 1995 for a review). Substitution, complementarity, and independence are measured by cross-price elasticity of demand and are represented by elasticity slopes that are positive, negative, or near zero, respectively. Studies to date have almost exclusively examined only pairs of products and in very few cases three concurrent commodities. Relevant to this application, the investigators examined the interaction of three commodities in one of their prior studies (Johnson, et al., 2004). Specifically, smokers had access to conventional cigarettes, reduced-nicotine cigarettes, and nicotine gum. When the price of conventional cigarettes increased, consumption of both reduced-nicotine cigarettes and nicotine gum increased even though their prices were fixed. Thus, reduced-nicotine

cigarettes and nicotine gum functioned as substitutes for conventional cigarettes. Indeed, by concurrently using both products, the smoker could reproduce different aspects of the conventional cigarette experience by consuming the reduced-nicotine cigarette (i.e., sensory effects associated with combustible tobacco smoke inhalation) and nicotine gum (i.e., central effects associated with nicotine ingestion). Importantly, reduced-nicotine cigarettes functioned as a better substitute than gum when each was offered as a substitute alone (the use of denicotinized cigarettes increased the most).

To inform how various products may interact, we have developed and tested a novel method called the Experimental Tobacco Marketplace. The Experimental Tobacco Marketplace is a systematic extension of similar marketplace methods used with other consumer products (e.g., food marketplaces used in obesity and other nutrition-related research; Epstein, Dearing, Roba, & Finkelstein, 2010). In experimental

marketplaces, multiple products are available and the experimenter controls the prices for each. These marketplaces can be either physical or virtual stores (similar to online retailers) and permit the examination of demand elasticity and intensity and degree of substitution or complementarity in consumer behavior under conditions that approximate naturalistic settings.

This study will extend findings from an ongoing project examining the effects of different concentrations of nicotine in cigarettes (0.4mg/g, 1.4mg/g, 2.5mg/g, 5.6mg/g, 17.4mg/g) on laboratory behavioral economic demand measures by including nicotine pouches (a novel product) and utilizing a within-subjects design. Employing this innovative Experimental Tobacco Marketplace, we propose to examine 2 concentrations of reduced-nicotine cigarettes (0.4 mg/g, 17.4mg/g) and tobacco-free nicotine pouches (2 mg and 8 mg). We will use a within-subjects design to allow smokers to sample each of the high dose and low dose cigarettes as well as a high dose and low dose of commercially available tobacco-free nicotine pouches. After sampling, participants will complete one Experimental Tobacco Marketplace session under four conditions: 1) increasing prices for the 0.4 mg/g cigarette with no other products available; 2) increasing prices for the 17.5 mg/g cigarette with no other products available; 3) increasing prices for the 0.4 mg/g cigarette with other products available; and 4) increasing prices for the 17.5 mg/g cigarette with other products available. The results of this experiment will be valuable in determining the degree and extent to which cigarette smokers may switch to a harm reduction alternative.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

The research team intends to publish the results of the current study in peer-reviewed journals.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Up to 100 current cigarette smokers will be recruited from the community surrounding Roanoke, VA. Eligible participants will be 21 to 65 years old, smoke from 5 to 40 cigarettes per day, have a breath carbon monoxide (CO) level of at least 10 ppm at intake, currently use or are willing to sample nicotine pouches, and have no immediate plans to quit smoking. Females who are planning pregnancy, pregnant, lactating, not willing to use contraception during the study, and individuals who have plans to move out of the area during the course of the experiment will be excluded from participation. Use of other tobacco/nicotine products will not be exclusionary. These minimally restrictive inclusion/exclusion criteria will allow for a broad range of participants and increase the generalizability to tobacco regulation of our eventual results.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

☐ **No,** go to question 3.3

☒ **Yes,** answer questions within table

IF YES
Are these records private or public? ☐ Public ☒ Private, describe the researcher's privilege to the records: **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.**

Will student, faculty, and/or staff records or contact information be requested from the University? ☒ No ☐ Yes, visit the following link for further information: http://www.policies.vt.edu/index.php (policy no. 2010)

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Participants will be recruited from the community via advertisements such as posted flyers, internet (e.g., Facebook or other websites), etc. To the extent possible, we will attempt to minimize obstacles to participation. For example, travel barriers may be addressed by providing transportation or parking costs for participants, and scheduling barriers will be minimized by offering a flexible study visit schedule. Compensation may be provided for travel costs and time. All methods and measures will be conducted using standard operating procedures, and all staff (including recruitment staff) will be provided with online human subjects training. We have a history of successful recruitment of cigarette smokers into research programs. All participants will enroll on a voluntary basis.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

Cigarette smokers who also currently use or would be willing to sample nicotine pouches will be recruited for this study. This population was chosen because the current experiment entails smoking cigarettes and nicotine pouches. Non-smokers would not be appropriate because nicotine and tobacco smoke may make individuals that do not regularly smoke feel ill. Women who can and may become pregnant (e.g., able to become pregnant and planning to become pregnant or don't use contraceptives) are excluded as the current tobacco products are investigational and risks to developing fetuses are unknown. Otherwise healthy individuals are sought to minimize any ill effects that exposure to nicotine and cigarette smoke may cause.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

☐ Verbal consent will be obtained from participants

☒ Written/signed consent will be obtained from participants

☐ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below) ☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

Potential participants will be provided with the written consent form prior to visiting a Virginia Tech facility (e.g., by email), if they wish. They will also be given additional time in a quiet room in a Virginia Tech facility to read the form. Virginia Tech affiliated research staff will review each element of the written consent form with the potential participant. The potential participant will be given the opportunity to ask questions and will have as much time as they need to decide whether they would like to participate in the study. They will be encouraged to speak with whomever they wish before making this decision. Staff 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 person obtaining consent will sign the consent form after the potential participant verbally states that s/he understands the conditions of the study, has no more questions, and chooses to participate.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Study team members that have been delegated this responsibility by the PI.

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

In a quiet room in a Virginia Tech facility.

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR? *Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.*

Consenting will occur prior to any study procedures.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

Prior to visiting the lab, participants will be given the option to receive a copy of the consent form before attending a consent session. They will be able to receive the consent copy via e-mail, mail, or in person if they wish. The potential participant will be given the opportunity to ask questions and will have as much time as they need to decide whether they would like to participate in the study. They will be encouraged to speak with whomever they wish before making this decision.

☐ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

We will first ask potential participants a series of brief screening questions to determine whether they will likely meet eligibility criteria. Individuals who are eligible based on the screening questionnaire will be scheduled for an informed consent session. Note that this phone screening script is used in many studies conducted here and is a broad screening to examine eligibility in a number of ongoing studies. The phone screen script is approved in VT IRB Protocol: 13-294.

The current study will take place over at least 2 laboratory sessions at the VTC's Addiction Recovery Research Center including the consent session (approximately 1 hour). Following informed consent, participants may also be asked to leave a baseline CO sample and urine sample (females only). The urine sample will be tested for pregnancy in females. Participants will be asked the following question: "Do you actively have plans to quit smoking cigarettes within the next 30 days?" If the participant answers "Yes",

they will be excluded from participation and provided the 1-800-QUITNOW (1-800-784-8669) hotline, which can connect callers to a variety of local resources for quitting. Participants will then complete approximately two laboratory sessions described below. Participants with active plans to quit may complete the assessment session but will not receive cigarettes/nicotine pouches nor return for the subsequent sessions.

Assessment session (approximately 1 hour). The first lab session will be the assessment session to collect information from participants on substance use patterns and severity, as well as the results of behavioral and cognitive tasks that we think may inform or compliment the results from the main study (see appendix for examples). This may be on the same day as the consent session.

Eligible participants will then receive two nicotine concentrations of the SPECTRUM investigational cigarette: NRC102/103 (~0.4mg/g cigarette in tobacco/menthol flavor depending upon participant's usual brand flavor) and NRC600/601 (~17.4mg/g cigarette in tobacco/menthol flavor) and two concentrations of nicotine pouch (ON! brand; 2 mg and 8 mg). Participants will receive approximately two days' worth of products to sample (based on the participant's normal amount of smoking as measured by the 30-day Timeline Followback), as well as take home assessments related to participants' subjective ratings of the products. This product sampling will include both investigational cigarettes and nicotine pouches matched to the participant's typical cigarette flavor (tobacco/menthol) and pouch flavor preferences (e.g., berry, mint).

During each day of the sampling period, participants will be contacted towards the end of the day via an Interactive Voice/Text Response service (either an automated call or automated text message) and will be asked how many of each product they used that day. This will allow more accurate daily monitoring of product usage compared to returning and retrospectively reporting their product use. We will also be able to investigate the correspondence between daily reporting and the Timeline Followback. During each IVR call, we will also ask a single question related to withdrawal feelings e.g., "On a scale of 0-9 with 0 being no withdrawal symptoms at all and 9 being extreme withdrawal symptoms, how would you rate your overall withdrawal symptoms today?"

Hypothetical Experimental Tobacco Marketplace sessions (approximately 15-30 min). Approximately 7 days following the completion of the sampling period, participants will return to the laboratory where they will bring back SPECTRUM cigarette butts and any unused products. We will ask them to complete a Hypothetical Experimental Tobacco Marketplace. During these Hypothetical Experimental Tobacco Marketplace sessions, participants will sit in front of a computer and respond to an online marketplace where they will be able to "purchase" a variety of nicotine products (e.g., investigational cigarettes, nicotine gum, snus, nicotine pouches). Importantly, the marketplace interface mimics what participants might encounter if they shopped online for these products. In order to obtain the behavioral economic measures described earlier (e.g., demand intensity, substitutability, complementarity), participants will complete a series of purchasing scenarios where the price of cigarettes (investigational cigarettes) is manipulated (approximately 6 prices) and all other nicotine products remain at a constant price. Participants will be given an allowance equal to seven days' worth of their typical expenditure on cigarettes and/or other tobacco products and will be asked to make purchases for the following seven days. Participants will be told to make these decisions as if they will actually receive the products, but participants will not actually receive the products they purchase.

The Hypothetical Experimental Tobacco Marketplace sessions will include:
1.Investigational cigarette A (0.4mg/g) increases in price (across separate blocks), with no other products available
2.Investigational cigarette B (17.4 mg/g) increases in price (across separate blocks), with no other products available
3. Investigational cigarette A (0.4mg/g) increases in price (across separate blocks), all other products' prices stay the same (no conventional cigarettes).
4.Investigational cigarette B (17.4 mg/g) increases in price (across separate blocks), all other products' prices stay the same (no conventional cigarettes).

During the last session, participants will complete several of the tasks completed during the assessment session (e.g., cigarette and nicotine pouch valuation, delay discounting tasks for hypothetical money, Timeline Followback, Fagerström Test of Cigarette Dependence).

At the end of the last session or when a participant withdraws from study, we will remind participants of the 1-800-QUITNOW hotline.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

All data will be collected and recorded with custom-built computer programs and/or standardized paper forms by trained study staff.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at *http://www.irb.vt.edu/documents/onlinepolicy.pdf*

☐ **No,** go to question 6.1

☒ **Yes,** answer questions within table

IF YES
Identify the service / program that will be used: ☐ www.survey.vt.edu, go to question 6.1 ☐ Blackboard, go to question 6.1 ☐ Center for Survey Research, go to question 6.1 ☒ Other **IF OTHER:** Name of service / program: **REDCap, Craigslist, Facebook** URL: **http://www.redcap.com/ , https://www.craigslist.org/, https://www.facebook.com** This service is… ☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm ☐ Approved by VT IT Security ☒ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages. ☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

One risk of participation is embarrassment that may come from answering sensitive questions related to medical, psychiatric, and/or drug use history. Loss of confidentiality is another risk of participation. Finally, there may be the potential for increased withdrawal symptoms related to less than usual nicotine intake.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Participants will be screened, using medical history and structured interviews, for a history of medical contraindications (e.g., pregnancy), and current unstable medical illnesses. The study will occur in one of our Virginia Tech facilities. Participants will be free to withdraw from the study at any time, and their refusal to continue will not affect other medical care associated with Carilion. Participants will be told that a risk may include increased withdrawal symptoms related to less than usual nicotine intake. 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 study products will be conducted and necessary referrals will be provided. Using only ID numbers and keeping all data in secure locations and/or in locked offices accessible only to trained study team members will protect confidentiality. Computer databases will have coded identifiers. These screening, monitoring, and confidentiality procedures have been in effect for more than 10 years and for more than 2,000 subjects across the various protocols employed by our group across various institutions.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

Participants might benefit from education about research participation. The project invoves minimal risk to confidentiality or other personal rights or to physical or emotional health. Thus, the expected benefits outweigh the very minimal risks to participants.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☒ **No**

☐ **Yes**

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR MENTALLY DISABLED PERSONS?

☒ **No,** go to question 7.3

☐ **Yes,** answer questions within table

IF YES
This research involves: ☐ Prisoners ☐ Pregnant women ☐ Fetuses ☐ Human in vitro fertilization ☐ Mentally disabled persons

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☒ **No**

☐ **Yes**

IF YOU ANSWERED "YES" TO ***ANY ONE*** OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT'S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☐ **No**

☒ **Yes,** to whom will identifying data be released? **Participant's identifying information (e.g., name, address, phone number) may be released to the VTC administrative offices and the VT Controller's office in order to process the petty cash reimbursements for participant payments.**

8.2 WILL ANY STUDY FILES CONTAIN PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select "Yes."

☐ **No,** go to question 8.3

☒ **Yes,** answer questions within table

IF YES
Describe if/how the study will utilize study codes: **Using only ID numbers and initials and keeping all data in locked offices will protect confidentiality. Computer databases will have coded identifiers and all computers will be password protected.**
If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] **be stored and who will have access?** **Master files linking subject names to study ID numbers will be accessible only to trained study team members delegated this access by the PI.**

Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.

The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.

8.3 WHERE WILL DATA BE STORED?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

All data and participant binders will be stored in a safe place to protect confidential participant information. Safe places will include locked filing cabinets or locked rooms accessible only to study personnel. The full

names of participants will not be listed on the outside of binders to protect confidentiality of study participants.

Electronic data will be saved in secure, limited access shared drives on password-protected computers accessible only to the research team.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Access to study data will be limited to study personnel who have completed the Virginia Tech IRB Human Subjects Tutorial and who have been delegated the responsibilties of data collection, management, or analyses by the PI.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

Data collected from this study 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.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

☐ **No,** go to question 9.1

☒ **Yes,** answer questions within table

IF YES

Does the study plan to obtain a Certificate of Confidentiality?

☒ No

☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form)

For more information about Certificates of Confidentiality, visit the following link:
http://www.irb.vt.edu/pages/coc.htm

Section 9: Compensation

For more information about compensating subjects, visit the following link: http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☐ **No,** go to question 10.1

☒ **Yes,** answer questions within table

IF YES
What is the amount of compensation? **Compensation for participation will be as follows: $20.00 for completion of informed consent** **$30.00 for the assessment session**

$1.00 for each day the participant responds to the Interactive Voice Response system (x7 total days) **$20.00 for the Hypothetical Experimental Tobacco Marketplace session** **$10.00 completion bonus** **Combined, the subjects could be compensated approximately up to $87 by completing all aspects of the experiment.** **To allow for payments that are both convenient and rapidly available, we may 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, the participant 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. This system will allow frequent, immediately available payments. Payments may also be made via check, however remote debit card payments will be used most often.**

Will compensation be prorated?

☒ Yes, please describe: **Subjects will be compensated based on what study procedures he/she has completed.**

☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link:

http://www.irb.vt.edu/pages/recordings.htm **10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?**

☒ **No,** go to question 11.1

☐ **Yes,** answer questions within table

IF YES
This project involves: ☐ Audio recordings only ☐ Video recordings only ☐ Both video and audio recordings
Provide compelling justification for the use of audio/video recording:

How will data within the recordings be retrieved / transcribed?
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?
Who will have access to the recordings?
Who will transcribe the recordings?

When will the recordings be erased / destroyed?

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☐ **No,** go to question 12.1

☐ **Yes,** answer questions within table

IF YES
Does this study involve conducting research with students of the researcher? ☐ No ☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation: *Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.*
Will the study need to access student records (e.g., SAT, GPA, or GRE scores)? ☐ No ☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☒ **No,** go to question 11.3

☐ **Yes,** answer questions within table

IF YES
Will study procedures be completed during school hours? ☐ No ☐ Yes **If yes,**

Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome: **Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:**
Is the school's approval letter(s) attached to this submission? ☐ Yes ☐ No, project involves Montgomery County Public Schools (MCPS) ☐ No, explain why: *You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). 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 accompany the approval request to the IRB.*

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

☒ **No,** go to question 12.1

☐ **Yes,** answer questions within table

IF YES
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded: ☐ Included ☐ Actively excluded, describe how the study will ensure that minors will not be included:
Will extra credit be offered to subjects? ☐ No ☐ Yes **If yes,** **What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?** **Include a description of the extra credit (e.g., amount) to be provided within question 9.1 ("IF YES" table)**

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?
Note: age constituting a minor may differ in other States.

☒ **No,** go to question 13.1

☐ **Yes,** answer questions within table

IF YES
Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide? ☐ No ☐ Yes, thoroughly explain how the study will react to such reports: *Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.*
Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)? ☐ No, **both** parents/guardians will provide their permission, if possible. ☐ No, **only one** parent/guardian will provide permission. ☐ Yes, describe below how your research meets **all** of the following criteria (A-D): Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The waiver will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the waiver: Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:
Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study? ☐ No ☐ Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors' previously provided assent and parents' permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects' data? If yes, explain how: *For more information about minors reaching legal age during enrollment, visit the following link: http://www.irb.vt.edu/pages/assent.htm*
*The procedure for obtaining assent from minors and permission from the minor's guardian(s) must be described in **Section 4** (Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at http://www.irb.vt.edu/pages/deception.htm

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

☒ **No,** go to question 14.1

☐ **Yes,** answer questions within table

IF YES
Describe the deception:

Why is the use of deception necessary for this project?
Describe the debriefing process:
Provide an explanation of how the study meets <u>all</u> the following criteria (A-D) for an alteration of consent: Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The alteration will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the alteration: Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception): *By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.*
The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☒ **No,** you are finished with the application

☐ **Yes,** answer questions within table

IF YES
From where does the existing data originate?
Provide a detailed description of the existing data that will be collected or studied/analyzed:
Is the source of the data public? ☐ No, continue with the next question ☐ Yes, you are finished with this application
Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects: ▪ Directly (e.g., by name, phone number, address, email address, social security number, student ID number), or **▪ Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or **▪ Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

☐ No, collected/analyzed data will be completely de-identified ☐ Yes, **If yes,** *Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.* **Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data?**

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

----------END----------