

Protocol Title:

Examining the generality of laboratory-based findings and their moderators using diverse samples from the International Tobacco Control (ITC) Policy Evaluation Project cohorts (Aims 3a and 3c)

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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.

Examining the generality of laboratory-based findings and their moderators using diverse samples from the International Tobacco Control (ITC) Policy Evaluation Project cohorts (Aims 3a and 3c)

PROTOCOL NUMBER:

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

24-520

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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 experiment is part of Project 3 of an NIH/NCI P01 Grant awarded to the Medical University of South Carolina. Virginia Tech is receiving a subcontract for Project 3. All of the human subject research activities for Project 3, including this experiment will be carried out by Virginia Tech.

VERSION NUMBER/DATE:

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

Version 1.0 04/30/2024

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?

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1.0 Study Summary

Study Title	Examining the generality of laboratory-based findings and their moderators using diverse samples from the International Tobacco Control (ITC) Policy Evaluation Project cohorts (Aims 3a and 3c)
Study Design	This study uses a mixed design (within-subject and between-group). Participants will complete a few behavioral questionnaires, and make hypothetical purchases of tobacco products in an online store under four different scenarios: a) control, b) NVPs at 1/2 market price, c) HTPs at 1/2 market price, and d) NPPs at 1/2 market price.
Primary Objective	To compare the effects of different tobacco/nicotine products (i.e., conventional cigarettes, NVPs, HTPs, and NPPs) on tobacco/nicotine purchasing and substitution in the Experimental Tobacco Marketplace, as a function of tobacco user type. To examine the generality of laboratory-based findings from a previous study that examined the same conditions across the US, Canada, and England.
Secondary Objective(s)	N/A
Study Population	Cigarette smokers and dual cigarette and NVP users
Sample Size	456 completers
Research Intervention(s)/ Investigational Agent(s)	A survey consisting of questionnaires and behavioral tasks.
Study Duration for Individual Participants	This will be a one-session study that participants will complete remotely including consent, ETM purchases, and assessments (approximately 30 minutes).
Acronyms and Definitions	NVP: Nicotine Vaping Product HTP: Heated Tobacco Product NPP: Nicotine Pouch Product ETM: Experimental Tobacco Marketplace ITC: International Tobacco Control (ITC) Policy Evaluation Project FBRI: Fralin Biomedical Research Institute

2.0 Objectives

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

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Purpose:

To compare the effects of different tobacco/nicotine products (i.e., conventional cigarettes, NVPs, HTPs, and NPPs) on tobacco/nicotine purchasing and substitution in the Experimental Tobacco Marketplace, as a function of tobacco user type.

To examine the generality of laboratory-based findings and their moderators from Study 1 (IRB#21-1046) using diverse samples from the US, CA, and EN, from the International Tobacco Control (ITC) Policy Evaluation Project cohorts.

2.2 State the hypotheses to be tested:

The primary hypotheses are: 1) purchasing of NVPs, HTPs, and NPPs will increase as the price of conventional cigarettes is increased (i.e., they will all serve as substitutes), 2) dual cigarette/NVP users, because they are multi-tobacco users, will show greater substitution than exclusive cigarette smokers, and 3) country-specific factors will result in shifts in the profiles of substitution and product purchasing.

3.0 Background

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

Cigarettes have long been the dominant tobacco product, and the vast majority of the tobacco-related harm comes from their combustion.[1] In recent years, alternative nicotine delivery systems have been developed. These products deliver nicotine without combusting tobacco and are marketed as alternative products for addicted smokers.[2] In the previous funding period, we focused on the emergence of NVPs. In this project, we add two additional product classes: HTPs and NPPs.

HTPs (sometimes called Heat Not Burn) are different from NVPs. HTPs heat reconstituted tobacco (tobacco not present within NVPs) at a temperature below the one required for combustion. Because the tobacco is not burned, exposure to harmful chemicals generated by cigarette smoke is substantially lower for HTPs.[3] The prevalence of HTP use in 2020 among current smokers and recent ex-smokers is estimated to be 2.7% in the US. [4] In Tokyo, where it has had the greatest success, IQOS captured 2.4% of the market share for tobacco, with >50% of smokers who tried the product switching entirely from cigarettes.[5] The limited data available on HTPs suggest that they are likely to serve as a substitute for conventional cigarettes.[6] Their role for dual cigarette/NVP users is unknown.

NPPs contain nicotine, but no tobacco,[7] and as a result, may present reduced harm compared to combustible and non-combustible tobacco products, such as smokeless tobacco and snus. A recent pharmacokinetic study showed that the two highest doses of NPP (Zyn) deliver nicotine quickly and at levels similar to traditional smokeless tobacco products.[8] In 2020, the prevalence of NPP use among current smokers and ex-smokers

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was estimated to be 0.7% in the US. [4] The most recent Nielsen data show that sales from these products are sharply on the rise. However, given that NPPs are oral nicotine products, rather than inhaled products like NVPs and HTPs, whether NPPs would effectively substitute for cigarettes or NVPs among cigarette smokers or dual users is unknown. Further, the strength of substitution for NPPs relative to NVPs and HTPs is unknown. Thus, utilization of NPPs in the ETM may provide data about substitutability that is prescient for understanding the implications of these products for tobacco control.

1. National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta (GA): : Centers for Disease Control and Prevention (US) 2014. <https://www.ncbi.nlm.nih.gov/pubmed/24455788>

2. Zeller M, Hatsukami D, Strategic Dialogue on Tobacco Harm Reduction Group. The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the US. *Tob Control* 2009;18:324–32. doi:10.1136/tc.2008.027318

3. IQOS. <https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system> (accessed 23 Jun 2020).

4. Li L, Borland R, Cummings KM, et al. Patterns of non-cigarette tobacco and nicotine use among current cigarette smokers and recent quitters: Findings from the 2020 ITC Four Country Smoking and Vaping Survey. *Nicotine Tob Res* Published Online First: 8 March 2021. doi:10.1093/ntr/ntab040

5. Caputi TL. Industry watch: heat-not-burn tobacco products are about to reach their boiling point. *Tob Control* 2016;26:609–10. doi:10.1136/tobaccocontrol-2016-053264

6. Adriaens K, Van Gucht D, Baeyens F. IQOSTM vs. e-Cigarette vs. Tobacco Cigarette: A Direct Comparison of Short-Term Effects after Overnight-Abstinence. *Int J Environ Res Public Health* 2018;15. doi:10.3390/ijerph15122902

7. Robichaud MO, Seidenberg AB, Byron MJ. Tobacco companies introduce ‘tobacco-free’ nicotine pouches. *Tob Control* Published Online First: 21 November 2019. doi:10.1136/tobaccocontrol-2019-055321

8. Lunell E, Fagerström K, Hughes J, et al. Pharmacokinetic comparison of a novel non-tobacco-based nicotine pouch (ZYN®) with conventional, tobacco-based Swedish snus and American moist snuff. *Nicotine Tob Res* Published Online First: 22 April 2020. doi:10.1093/ntr/ntaa068

3.2 Describe any relevant preliminary data:

The Experimental Tobacco Marketplace (ETM) [1], a novel method recently developed, permits estimates of the effects of new policies and products on consumption and substitution in the tobacco marketplace. This methodology places the mix of products, prices, and specific policies under experimental control so as to provide estimates of novel policies obtained under conditions that simulate “real world” circumstances. This approach provides insight into how a given policy may alter consumption, preferences, and substitution among tobacco products. Different policies have been examined with this methodology in adult smokers, as part of the previous funding period. Study 1

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examined the impact of e-liquid nicotine strength and showed that the substitutability between cigarettes and NVPs increased as a function of e-liquid strength. The 24mg/mL strength resulted in the greatest substitutability ($p < 0.001$; $f = 1.05$).^[2] Study 2 examined cigarette taxes and e-liquid subsidies. It showed that cigarette taxes decreased cigarette purchases ($p = 0.005$; $f = 0.45$).^[3] Interestingly, e-liquid subsidies had no effects on cigarette purchases, but increased e-liquid purchases ($p = 0.013$; $f = 0.44$). Study 3 used a hypothetical ETM and replicated the taxes and subsidies conditions from Study 2 among exclusive cigarette smokers and dual cigarette/NVP users in an international context as part of the ITC survey. Analysis of country-specific differences have yet to be explored, however, the US cohort replicates the findings of the lab-based ETM. Note, the effects of taxes on cigarette purchases observed in Studies 2 and 3 replicate and demonstrate the generality of our findings as related to prior econometric analysis of the impact of national and state taxes.^[4] This replication provides an example of reverse translational research demonstrating that the ETM can reflect effects observed in larger populations.^[5] Study 4 investigated the effects of NVP use in smoke-free environments on product choice. The results suggest that permitting NVP use in the workplace increased e-liquid purchase on average ($p < 0.001$; $f = 0.56$), but nicotine concentration had no effect on e-liquid demand intensity. Cigarette demand was unaltered across conditions.^[6] This study suggests that allowing NVP use in the workplace may increase the demand for e-liquid without affecting purchases of conventional cigarettes. Collectively, and importantly for the proposed study, our ETM work shows that the substitution between products is dependent upon several factors (nicotine strength, price of the substitutable product, and the type and number of products in the marketplace). In these studies, we change the price as an expeditious, effective, and quantifiable method to promote change. With that change, we can ascertain the likelihood that smokers will defend their consumption or substitute it for another product. In doing so, we can estimate the consequences of a policy constraint before implementation. In study 1 conducted in the laboratory, we confirmed that: 1) purchasing of NVPs, HTPs, and NPPs increased as the price of conventional cigarettes was increased (i.e., they will all serve as substitutes), 2) the effect was largest when those alternative products were at a reduced price (1/2 MP - conditions replicated in this study).

1. Bickel WK, Pope DA, Kaplan BA, et al. Electronic cigarette substitution in the experimental tobacco marketplace: A review. *Prev Med* 2018;117:98–106. doi:10.1016/j.ypmed.2018.04.026
2. Pope DA, Poe L, Stein JS, et al. Experimental tobacco marketplace: substitutability of e-cigarette liquid for cigarettes as a function of nicotine strength. *Tob Control* Published Online First: 18 April 2018. doi:10.1136/tobaccocontrol-2017-054024
3. Pope DA, Poe L, Stein JS, et al. The Experimental Tobacco Marketplace: Demand and Substitutability as a Function of Cigarette Taxes and E-Liquid Subsidies. *Nicotine Tob Res* under review.
4. Chaloupka FJ, Grossman M, Bickel WK, et al. The Economic Analysis of Substance Use and Abuse: An Integration of Econometric and Behavioral Economic Research. Published Online First: 1 January 1999. <https://www.nber.org/books/cha199-1.pdf> (accessed 7 Aug 2020).

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5. Shakhnovich V. It's Time to Reverse our Thinking: The Reverse Translation Research Paradigm. Clin Transl Sci 2018;11:98–9. doi:10.1111/cts.12538

6. Freitas Lemos R, Stein JS, Pope DA, Brown J, Feinstein M, Stamborski KM, Tegge AN, Heckman BW, Bickel WK. E-liquid Purchase as a Function of Workplace Restriction in the Experimental Tobacco Marketplace. Exp Clin Psychopharmacol; Advance online publication. <https://doi.org/10.1037/pha0000444>

- 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 demand for the most harmful products. No study to date has experimentally compared the effects of conventional cigarettes, NVPs, HTPs, and NPPs on tobacco/nicotine purchasing and substitution. A priori knowledge of substitutability across novel and widely used tobacco products may forecast the impact of policies on product switching.

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_khh511SQQjhGDDGHZcOPRHR5Tw/edit?usp=sharing

Substitutability: cigarettes, NVPs, HTPs, and NPPs will be compared to assess substitutability as a function of tobacco user type across different regulatory environments.

- 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.):*

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This study will recruit adults/young adults who regularly smoke cigarettes and who regularly smoke cigarettes and use NVPs. 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.

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):

This study uses a mixed design (within-subject and between-group). Participants will complete a few behavioral questionnaires, and make hypothetical purchases of tobacco products in an online store under four different scenarios: a) control, b) NVPs at 1/2 market price, c) HTPs at 1/2 market price, d) and NPPs at 1/2 market price.

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):

A within-between subject analysis of variance (ANOVA) will test for differences in substitution and demand measures between user types (exclusive cigarette smokers and dual cigarette/NVP users) and relative price scenario (e.g., ½ market price for HTPs). We will test for the interaction between the relative price scenarios and each user type, suggesting a difference in how each user type responds to price scenarios. In addition, we will add a covariate for country. Moreover, we will use other tobacco related measures collected by the ITC primary survey to understand the possible influence of these variables on purchasing in the ETM. Order effects will be included in all models to account for the balanced Latin square design for counterbalancing the ETM conditions within the session. We will perform post-hoc contrasts to compare user types, based on our hypotheses.

Additional analyses might be conducted.

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.*

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- *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.*

Recruitment: The sample that we plan on using for this study, which is to be conducted online in 3 different countries, will be recruited and screened by contracted survey firms. The ITC project has conducted cohort studies in the past of tobacco users and we will use their databases to recruit the sample needed for this study. Specifically, participants from the US, Canada, and England will be recruited and screened by IPSOS Public Affairs, LLC, Leger Marketing, and Ipsos UK, respectively. Participants who complete the main ITC survey, will be invited to complete a bonus survey online that incorporates both the assessment and ETM trials described in this protocol.

Location of study: The research procedures will be performed remotely. The study survey will be prepared by our VT team. Recruitment will be by the survey firms mentioned above and closely monitored by our team. All participants will enroll on a voluntary basis and consent electronically 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.*

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This study does involve experimental manipulation of nicotine/tobacco product price and availability in a hypothetical online store to understand consumer's behavior. No drugs or devices will be provided to participants.

- 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:*

N/A

- 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:*

N/A

- 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:*

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

N/A

8.0 Procedures Involved

8.1 Describe and explain the study design:

This study uses a mixed design (within-subject repeated measures and between-group). In a one-session survey, participants will complete assessments and purchase tobacco products in a hypothetical ETM. All participants will complete four ETM conditions, all of which include approximately five trials assessing different prices of their preferred cigarette. In each ETM condition, participants will purchase tobacco/nicotine products for a 7-day period.

ETM conditions include:

- a) control (NVPs, HTPs, and NPPs at market price),
- b) NVPs at 1/2 market price,
- c) HTPs at 1/2 market price, and
- d) NPPs at 1/2 market price.

Participants will be exposed to these conditions across purchasing scenarios in a counterbalanced order.

Every participant will complete questionnaires on a computer, tablet or cell phone.

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 who meet inclusion criteria will be invited to participate and will be redirected from the main ITC survey to a bonus survey that will include questionnaires, smoking-related assessments, and ETM purchasing trials.

A Qualtrics survey will administer:

2) smoking-related assessments

a) timeline follow back, to assess previous month recent smoking, e-cigarette use and consumption of nicotine products, and to determine ETM budget

b) e-cigarette use and perceptions

c) tobacco awareness (for NVP, HTP, and NPP)

d) intention to transition or quit

3) the ETM;

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Participants will make hypothetical purchases of tobacco products to use throughout the next 7 days. Participants will complete a total of 20 purchasing trials each for 7 days' worth of products. They will be exposed to 4 conditions with their preferred cigarettes increasing in price. The following conditions will be presented in a randomized order:

- a) control (NVPs, HTPs, and NPPs at market price,
- b) NVPs at 1/2 market price,
- c) HTPs at 1/2 market price, and
- d) NPPs at 1/2 market price.

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.

Demographic questions answered in the main survey are available to investigators upon request to the ITC team.

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.

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All tasks can be performed on a computer, tablet or cell phone. Only study personnel will have access to the collected data.

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 all 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 electronic data, will be stored in secure places to protect confidential participant information. Secured places will include password-protected databases

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accessible only to study personnel. Additionally, all data will be backed up on secure password-protected servers. Moreover, all data will be quality controlled in preparation for data analyses.

Data collected from this study will be retained for at least 5 years following study closure. Identifiers will be destroyed 3 years following final publication of the data. 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.

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. Only de-identified participant data collected will be shared 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 acknowledgement; 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:

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The VTC study team will not have access to any identifiers. Participants will be recruited and assigned a study ID by the survey firms that are thereafter associated with all collected data. The electronic de-identified data is stored on the shared servers which are password protected.

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

<input type="checkbox"/>	Name
<input type="checkbox"/>	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)
<input type="checkbox"/>	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+)
<input type="checkbox"/>	Phone numbers
<input type="checkbox"/>	Fax numbers
<input type="checkbox"/>	Electronic mail addresses (e-mail)
<input type="checkbox"/>	Social Security numbers
<input type="checkbox"/>	Medical record numbers
<input type="checkbox"/>	Health plan beneficiary numbers
<input type="checkbox"/>	Account numbers
<input type="checkbox"/>	Certificate/license numbers
<input type="checkbox"/>	Vehicle identifiers and serial numbers, including license plate numbers
<input type="checkbox"/>	Device identifiers and serial numbers
<input type="checkbox"/>	Web Universal Resource Locators (URLs)
<input type="checkbox"/>	Internet protocol (IP) address numbers
<input type="checkbox"/>	Biometric identifiers, including finger and voice prints (audio recording)
<input type="checkbox"/>	Full face photographic images and any comparable images (including video recording)
<input type="checkbox"/>	Student record number or identification number
<input type="checkbox"/>	User name for online or computer accounts
<input type="checkbox"/>	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

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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.*

Participant's schedule: the participation of one subject is expected to take approximately 30 minutes in a single session.

Study timeline: enrollment and data collection are expected to take about 3 months.

The study team has projected this study to take approximately 1 year 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:

Participants will be first screened by the ITC project after completion of the main survey. Eligible participants will be invited to participate in this study and have access to a survey link.

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

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aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France):

A sample of 456 adults participants from the US, EN, and CA will complete the study (76 smokers and 76 dual users from each of the three countries).

Eligibility (filters:)

Smokers only must satisfy the following criteria:

- a. From CA, US, or EN (country=CA, EN, or US)
- b. At least 21 years old (ageSD>20)
- c. Smoking daily (FR309v=10)
- d. Smoking mostly or about equal amounts of factory-made cigarettes (vs. Roll Your Own) (FR300=1-3)
- e. Does not currently vape (EC309v=40-70)

Dual users must satisfy the following criteria:

- a. From CA, US, or EN (country=CA, EN, or US)
- b. At least 21 years old (ageSD>20)
- c. Smoking daily (FR309v=10)
- d. Smoking mostly or about equal amounts of factory-made cigarettes (vs. Roll Your Own) (FR300=1-3)
- e. Vapes Daily (EC309v=10)

There will be no additional exclusion criteria for this study.

Based on our prior experience with the ITC, we should be able to fill the requested sample size.

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. We will not include individuals under the age of 21 in compliance with Federal laws. Minors, prisoners, and adults not capable to consent on their own behalf will not be part of the recruitment. Pregnant women will not be excluded and might be invited for 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.*

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Pregnant women might participate in the study if they meet the inclusion criteria, although pregnant women will not be directly recruited because of their status. There are no procedures in this study that can represent a threat to their rights or welfare.

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 size is based on repeated measures within-between interaction ANOVA design using a small effect size ($f=0.1$) to account for increased variability in the population and 80% power. Note the effect sizes observed in preliminary data collected from laboratory based studies ranged from $f=0.29$ to $f=1.05$. Given that the products (i.e., NVP and HTPs) used in these experiments are untested and we are sampling from a more diverse population, we conservatively selected a small effect size of $f=0.1$. In order to account for multiple testing, we will control for five comparisons; therefore, we use an alpha of 0.01. We require $n=456$ (76/cohort) participants to complete the study when using repeated measures with 6 cohorts (3 countries x 2 user type) and 2 measurements per participant. Attrition is not included in these final sample sizes because the study will be completed in one session. Note that this Aim includes more than two measurements per participant, but only two were considered in the calculations to maximize power.

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:

Every participant who completes the main survey will be screened for the bonus study and invited to participate. We will use a quota system to assess if more participants of that specific tobacco user type are needed. A total of 456 participants will complete the study.

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

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All participants will undergo one entire study session unless they withdraw consent.

15.0 Recruitment Methods

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

Participants who complete the main ITC survey and meet eligibility criteria will be invited to complete a bonus survey.

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):

As stated above, the source will be the ITC cohorts.

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

ITC completers who meet eligibility criteria will see an invite to a bonus survey at the end of the main survey.

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.*

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Invitation is attached.

Compensation: Participants will be paid through the survey firms upon completion of our survey. The survey firms are paid a flat rate per participant; when participants finish our survey, the firm pays the participants according to their own policies and protocols. Participants will be paid approximately \$8 USD or equivalent value, \$8CAD or equivalent in panel points or Air Miles or Aeroplan reward miles, or in England the standard points provided to their panelists.

16.0 Withdrawal of Subjects

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

Every participant who gives their consent will have the opportunity to complete 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):

N/A

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):

Participants can stop completing the survey without submitting it at any time. In this case, a participant will be withdrawn from the entire 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

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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 participant considers sensitive. Some of our questions will ask for information about substance use.
2. Possible discomfort: There is also the possibility that participant 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.

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 electronically using standard operating procedures. All participants will enroll on a voluntary basis and read an IRB-approved consent form prior to study participation. Consent to participate in this study will be implied with submission of the assessment.

Protections against risk. Participants will be free to withdraw from the study at any time.

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The risks enumerated above will be addressed by the following:

1. Possible embarrassment: Participants may discontinue at any time.

2. Possible discomfort: Participants can take breaks, if desired.

3. Loss of confidentiality: The use of study ID for participants will protect confidentiality. Password protected computer databases will have coded identifiers. Master databases linking subject names to study ID are only available through survey firm. VT will have no access.

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:

N/A

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

N/A

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:

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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 the health of people 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.

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 all study personnel, including the PI, will be in attendance.

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*

Survey firm will only provide demographics data from completers. See "Standard Demographics" attached. No biospecimens will be obtained.

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.:

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To secure study data computer databases will have coded identifiers, only ID numbers will be used and data will be kept in secure locations. 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. In addition, this project is included in the NIH grants' 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?*

As stated previously, data collected from this study will be retained for at least 5 years following study closure. Identifiers will be destroyed 3 years following final publication of the data.

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):

No private information will be collected in this study. Private information is collected and protected by the survey firms. Procedures to keep all other the information safe are described in section 9.4.

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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):

Participants will voluntarily complete the study in the place of their choice on their own time using a computer, tablet or cell phone. 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:

The VT team will provide the ITC with study's IDs from participants that completed the survey. The ITC will then provide demographics and any other requested measures collected in the main survey. No private information will be exchanged.

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.

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).*

N/A

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

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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.

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*

An invitation to participate in this study will be sent to participants who complete the main ITC survey. If they are interested in completing the study, they will be redirected to a bonus survey and will be able to read specific information about the study. Consent for the bonus survey will be implied with submission of the survey.

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Consent will take place on the internet and through the portal in which the survey will be administered. That is, we will include detailed information about the nature of the study prior to the assessment beginning. The potential participant will be instructed to read that information and by continuing with the assessment give consent.

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-*

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- 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-

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- 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:

Consent will not be documented in writing.

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):

As stated above, consent will take place on the internet and through the portal in which the survey will be administered. That is, we will include detailed information about the nature of the study prior to the assessment beginning. The potential participant will be instructed to read that information and by continuing with the assessment give consent.

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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:*

Electronic informed consent 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. Warren Bickel, who will assume full responsibility for all aspects of the project, including design and participant eligibility. Dr. Bickel will oversee study procedures. He will also oversee and delegate to the Co-Investigators and other study team members the responsibility of monitoring data collection. Behavioral data analysis will be overseen by Dr. Bickel and conducted by the Co-Is and the Statistician.

All staff involved in planning and monitoring of this study will have completed the IRB Human Subject Protection Training and Good Clinical Practice Training. Documentation of training will be maintained.

24-520 Examining the generality of laboratory-based findings and their moderators using diverse samples from the International Tobacco Control (ITC) Policy Evaluation Project cohorts (Aims 3a and 3c)

All methods and measures will be conducted using standard operating procedures. All participants will enroll on a voluntary basis and read an IRB-approved consent form prior to study participation. Consent to participate in this study will be implied with submission of the assessment.

This survey will be administered remotely and participants will not be required to visit our facilities.

Study team meet on a regular basis and any issues will be discussed and addressed all study personnel, including the PI.

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.

[Click here to provide a response.](#)